



The studies listed below are being conducted by Arizona Oncology Services Foundation at all 5 Arizona Oncology Services Centers (AOS) across the Metropolitan Phoenix area, as well as, the Radiation Oncology Department at St. Joseph's Hospital and Medical Center, which is staffed by AOS Physicians. These study descriptions are taken from the National Cancer Institute (NCI) Clinical Trial list site. Underlined study titles and words are linked directly to the NCI website to help you find additional information and definitions. If you need additional information please call or email Terry Thomas, MS, CCRC at 602-240-3383 or tthomas@azoncology.com.

PRIMARY BRAIN CANCER PROTOCOLS

[Observation or Radiation Therapy in Treating Patients With Grade I, Grade II, or Grade III Meningioma RTOG 0539](#)

Purpose: Sometimes a tumor may not need treatment until it progresses. In this case, observation may be sufficient. Specialized radiation therapy that delivers a high dose of radiation directly to the tumor, such as 3-dimensional conformal radiation therapy and intensity-modulated radiation therapy, may kill more tumor cells and cause less damage to normal tissue. It is not yet known whether observation is more effective than radiation therapy in treating patients with meningioma.

This phase II trial is studying observation to see how well it works compared with radiation therapy in treating patients with grade I, grade II, or grade III meningioma.

Eligibility criteria include the following:

- At least 18 years old
- No more than 3 months since MRI
- No cancer outside the brain or hemangiopericytoma
- No previous radiation therapy to the head
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will be assigned to one of three groups.

- Patients in group one will undergo observation.
- Patients in group two will undergo 3-dimensional conformal radiation therapy or intensity-modulated radiation therapy 5 days a week for 6 weeks.
- Patients in group three will undergo intensity-modulated radiotherapy 5 days a week for 6 weeks.

After finishing treatment, patients will be evaluated every 3-6 months for 3 years and once a year for 10 years.

[Radiation Therapy With or Without Temozolomide in Treating Patients With Low-Grade Glioma E3F05](#)

Purpose: Radiation therapy uses high-energy x-rays to kill tumor cells. Specialized radiation therapy that delivers a high dose of radiation directly to the tumor may kill more tumor cells and cause less damage to normal tissue. Drugs used in chemotherapy, such as temozolomide, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. It is not yet known whether radiation therapy is more effective when given together with or without temozolomide in treating patients with low-grade glioma. This randomized phase III trial is studying radiation therapy so see how well it works when given together with or without temozolomide in treating patients with low-grade glioma.

Eligibility criteria include the following:

- At least 18 years old
- No previous radiation therapy, chemotherapy, or radiosurgery for the brain tumor
- At least 2 weeks since brain surgery
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will be randomly assigned (have an equal chance of being placed) to one of two treatment groups.

- Patients in group one will undergo radiation therapy 5 days a week for 5½ weeks.
- Patients in group two will undergo radiation therapy 5 days a week and receive temozolomide by mouth once a day for 5½ weeks. Beginning 4 weeks later, they will receive temozolomide alone by mouth once a day on days 1-5. Treatment with temozolomide may repeat every 4 weeks for up to 12 courses.

Some patients will undergo quality-of-life assessments and visual, attention, language, memory, and fine- motor skills assessments at the beginning of the study and then once a year. Patients will undergo tumor tissue sample collection at the beginning of the study for laboratory studies. Blood samples and additional tumor tissue samples may also be collected. After finishing treatment, patients will be evaluated periodically for up to 15 years.

Radiation Therapy With or Without Temozolomide in Treating Patients With Anaplastic Glioma RTOG 0834

Purpose: Radiation therapy uses high-energy x-rays to kill tumor cells. Drugs used in chemotherapy, such as temozolomide, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Giving radiation therapy together with temozolomide may kill more tumor cells. It is not yet known whether giving temozolomide during and/or after radiation therapy is more effective than radiation therapy alone in treating anaplastic glioma. This randomized phase III trial is studying giving temozolomide during and/or after radiation therapy to see how well it works compared to radiation therapy alone in treating patients with anaplastic glioma.

Eligibility criteria include the following:

- At least 18 years old
- No previous chemotherapy, including Gliadel Wafer
- No previous radiation therapy to the brain
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will be randomly assigned (have an equal chance of being placed) to one of four treatment groups.

- Patients in group one will undergo radiation therapy once a day, 5 days a week for 6½ weeks.
- Patients in group two will undergo radiation therapy once a day, 5 days a week and receive temozolomide by mouth once a day for 6½ weeks.
- Patients in group three will undergo radiation therapy once a day, 5 days a week for 6½ weeks. Four weeks after finishing radiation therapy, they will receive temozolomide by mouth once a day for 5 days. Treatment with temozolomide may repeat every 4 weeks for up to twelve courses.
- Patients in group four will undergo radiation therapy once a day, 5 days a week and receive temozolomide by mouth once a day for 6½ weeks. Four weeks after finishing radiation therapy and temozolomide, they will receive temozolomide by mouth once a day for 5 days. Treatment with temozolomide may repeat every 4 weeks for up to twelve courses.

Patients will fill out quality of life questionnaires at the beginning of the study, 4 weeks after finishing radiation therapy, and every 3 months thereafter.

Tissue samples will be collected at the beginning of the study for laboratory studies.

After finishing treatment, patients will be evaluated every 3 months.

Radiation Therapy or Radiation Therapy and Temozolomide or Temozolomide Alone in Treating Patients With Newly Diagnosed Anaplastic Glioma NCCTG 0577

Purpose: Radiation therapy uses high-energy x-rays to kill tumor cells. Drugs used in chemotherapy, such as temozolomide, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. It is not yet known whether giving temozolomide alone, radiation therapy alone, or temozolomide together with radiation therapy is more effective in treating anaplastic glioma. This randomized phase III trial is comparing giving temozolomide alone, radiation therapy alone, or Temozolomide together to see which works best in treating patients with newly diagnosed anaplastic glioma.

Eligibility criteria include the following:

- At least 18 years old
- No previous chemotherapy, radiation therapy, or surgery for this cancer
- At least 2 weeks since surgery
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will be randomly assigned (have an equal chance of being placed) to one of three treatment groups.

- Patients in group one will undergo radiation therapy once a day, 5 days a week for 6 weeks.
- Patients in group two will undergo radiation therapy once a day, 5 days a week and receive temozolomide by mouth once a day for 6 weeks. Four weeks after finishing radiation therapy and temozolomide, they will receive temozolomide by mouth once a day for 5 days. Treatment with temozolomide may repeat every 4 weeks for up to twelve courses.
- Patients in group three will receive temozolomide by mouth once a day for 5 days. Treatment may repeat every 4 weeks for up to twelve courses.

Patients will fill out neurocognitive and quality of life questionnaires at the beginning of the study, and periodically thereafter.

Previously collected tissue samples will be will be studied in the laboratory.

After finishing treatment, patients will be evaluated periodically.

Dasatinib in Treating Patients With Recurrent Glioblastoma Multiforme or Gliosarcoma RTOG 0627

Purpose: Dasatinib may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. This phase II trial is studying how well dasatinib works in treating patients with recurrent glioblastoma multiforme or gliosarcoma.

Eligibility criteria include the following:

- At least 18 years old
- Received previous treatment with radiation therapy and temozolomide
- More than 4 weeks since radiation therapy
- More than 2 weeks since temozolomide
- No previous stereotactic radiosurgery or brachytherapy
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will receive dasatinib by mouth twice a day. Treatment may continue for as long as benefit is shown.

Patients will undergo tumor biopsies before beginning treatment and may undergo tumor biopsies after finishing treatment for laboratory studies.

After finishing treatment, patients will be evaluated periodically.

Temozolomide and Radiation Therapy With or Without Bevacizumab in Treating Patients With Newly Diagnosed Glioblastoma or Gliosarcoma RTOG 0825

Purpose: Drugs used in chemotherapy, such as temozolomide, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Radiation therapy uses high-energy x-rays to kill tumor cells. Monoclonal antibodies, such as bevacizumab, can block tumor growth in different ways. Some block the ability of tumor cells to grow and spread. Others find tumor cells and help kill them or carry tumor-killing substances to them. It is not yet known whether temozolomide and radiation therapy are more effective when given together with or without bevacizumab in treating glioblastoma or gliosarcoma. This randomized phase III trial is studying temozolomide and radiation therapy to compare how well they work when given together with or without bevacizumab in treating patients with newly diagnosed glioblastoma or gliosarcoma.

Eligibility criteria include the following:

- At least 18 years old
- No more than 5 weeks since undergoing surgery to remove the tumor
- No recurrent cancer
- No previous chemotherapy for head and neck cancer
- No previous temozolomide, bevacizumab, or Gliadel wafers
- More than 4 weeks since surgery or open biopsy (other than surgery to remove the tumor)

Treatment/Intervention: Patients will be randomly assigned (have an equal chance of being placed) to one of two treatment groups.

- Patients in group one will undergo radiation therapy 5 days a week for 6 weeks. At the same time, they will also receive temozolomide by mouth once a day for up to 7 weeks. Beginning 4 weeks later, patients will receive temozolomide by mouth on days 1-5. Treatment with temozolomide may repeat every 4 weeks for up to 12 courses. Beginning in week 4 of radiation therapy, patients will also receive a 30- to 90-minute infusion of a placebo every 2 weeks until finishing temozolomide.
- Patients in group two will undergo radiation therapy 5 days a week for 6 weeks. At the same time, they will also receive temozolomide by mouth once a day for up to 7 weeks. Beginning 4 weeks later, patients will receive temozolomide by mouth on days 1-5. Treatment with temozolomide may repeat every 4 weeks for up to 12 courses. Beginning in week 4 of radiation therapy, patients will also receive a 30- to 90-minute infusion of bevacizumab every 2 weeks until finishing temozolomide.

Some patients may undergo MRI before the start of treatment, during treatment, and after completion of treatment. After finishing treatment, patients will be evaluated every 3 months for 1 year, every 4 months

METASTATIC CANCER to the BRAIN PROTOCOLS

(Cancer that has spread to the brain from another site)

Stereotactic Radiation Therapy With or Without Whole-Brain Radiation Therapy in Treating Patients With Brain Metastases NCCTG 0574

Purpose: Stereotactic radiation therapy can send x-rays directly to the tumor and cause less damage to normal tissue. Radiation therapy uses high-energy x-rays to kill tumor cells. It is not yet known whether stereotactic radiation therapy is more effective with or without whole-brain radiation therapy in treating patients with brain metastases. This randomized phase III trial is studying stereotactic radiation therapy and whole-brain radiation therapy to see how well they work compared with stereotactic radiation therapy alone in treating patients with brain metastases.

Eligibility criteria include the following:

- At least 18 years old
- One to three brain metastases
- Metastases are from tumors outside the brain (such as the lung, breast, or prostate)
- Measurable disease
- No primary germ cell tumor, lymphoma, or small cell carcinoma
- No leptomeningeal metastases
- No previous radiation therapy to the brain
- No previous surgery to remove brain metastases
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will be randomly assigned (have an equal chance of being placed) to one of two treatment groups.

- Patients in group one will undergo stereotactic radiation therapy.
- Patients in group two will undergo stereotactic radiation therapy. Beginning no more than 2 weeks later, they will undergo radiation therapy to the entire brain 5 days a week for 2½ weeks.

Quality of life, ability to function independently, and ability to think and reason will be assessed before the first treatment; at the beginning of each treatment; at 6 and 12 weeks; at 6, 9, 12, and 16 months; and once a year until year 5.

Memantine in Preventing Side Effects in Patients Undergoing Whole-Brain Radiation Therapy for Brain Metastases From Solid Tumors RTOG 0614

Purpose: Memantine may be able to decrease side effects caused by whole-brain radiation therapy. It is not yet known if memantine is effective in preventing side effects caused by whole-brain radiation therapy. This randomized phase III trial is studying memantine to see how well it works compared to a placebo in preventing side effects caused by whole-brain radiation therapy in patients with brain metastases from solid tumors.

Eligibility criteria include the following:

- At least 18 years old
- At least 2 weeks but no more than 8 weeks since previous therapy for brain metastases, including radiosurgery or surgical resection
- More than 2 weeks since chemotherapy
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will be randomly assigned (have an equal chance of being placed) to one of two treatment groups.

- Patients in group one will undergo whole-brain radiation therapy 5 days a week for 3 weeks. They will also receive memantine by mouth once a day for 24 weeks starting on day 1 of radiation therapy.
- Patients in group two will undergo whole-brain radiation therapy 5 days a week for 3 weeks. They will also receive a placebo by mouth once a day for 24 weeks starting on day 1 of radiation therapy.

After finishing treatment, patients will be evaluated at 6 months, every 4 months for 1 year, every 6 months for 2 years, and once a year thereafter.

BREAST CANCER PROTOCOLS

Radiation Therapy With or Without Trastuzumab in Treating Women With Ductal Carcinoma In Situ Who Have Undergone Lumpectomy NSABP B43

Purpose: Monoclonal antibodies, such as trastuzumab, can block tumor growth in different ways. Some block the ability of tumor cells to grow and spread. Others find tumor cells and help kill them or carry tumor-killing substances to them. Radiation therapy uses high-energy x-rays to kill tumor cells. It is not yet known whether radiation therapy is more effective with or without trastuzumab in treating ductal carcinoma in situ. This randomized phase III trial is studying radiation therapy to see how well it works compared with or without trastuzumab in treating women with ductal carcinoma in situ who have undergone lumpectomy.

Eligibility criteria include the following:

- At least 18 years old
- HER2 receptor positive
- No more than 4 months since surgery
- Does not require mastectomy
- No cancer or ductal carcinoma in situ in the other breast
- No previous radiation therapy to the breast
- No previous drugs such as daunorubicin, doxorubicin, or epirubicin
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will be randomly assigned (have an equal chance of being placed) to one of two treatment groups.

- Patients in group one will undergo whole-breast radiation therapy for 5 to 6 weeks.
- Patients in group two will receive a 30- to 90-minute infusion of trastuzumab in weeks 1 and 4. They will also undergo whole-breast radiation therapy for 5 to 6 weeks.

Tumor tissue samples will be studied in the laboratory.

After finishing treatment, patients will be evaluated every 6 months for 5 years and once a year for 5 years

Phase III Randomized Study of Adjuvant Whole Breast Versus Partial Breast Irradiation in Women With Ductal Carcinoma In Situ or Stage I or II Breast Cancer NSABP B-39/RTOG 0413

Purpose: Radiation therapy uses high-energy x-rays to kill tumor cells. Giving radiation therapy in different ways may kill any tumor cells that remain after surgery. It is not yet known whether whole breast radiation therapy is more effective than partial breast radiation therapy in treating breast cancer. This randomized phase III trial is studying whole breast radiation therapy to see how well it works compared to partial breast radiation therapy in treating women who have undergone surgery for ductal carcinoma in situ or stage I or stage II breast cancer.

Eligibility criteria include the following:

- At least 18 years old
- Has undergone surgery to remove the tumor
- No Paget's disease of the nipple
- Any estrogen receptor or progesterone receptor status
- No previous biological therapy, chemotherapy, or radiation therapy for this cancer
- No previous radiation therapy to the breast or chest
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will be randomly assigned (have an equal chance of being placed in one of two treatment groups).

- Patients in group one will receive whole breast radiation therapy once a day 5 days a week for 5-7 weeks.
- Patients in group two will receive partial breast radiation therapy twice a day on 5 days over a period of 5-10 days.
- In both groups, patients may receive chemotherapy at least 2 weeks before or after radiation therapy. Some patients may also receive hormone therapy for at least 5 years.

Patients will be evaluated at 1 month, every 6 months for 5 years, and once a year thereafter.

Hormone Therapy With or Without Combination Chemotherapy in Treating Women Who Have Undergone Surgery for Node-Negative Breast Cancer (The TAILORx Trial)

Purpose: Estrogen can cause the growth of breast cancer cells. Hormone therapy may fight breast cancer by blocking the use of estrogen by the tumor cells or by lowering the amount of estrogen the body makes. Drugs used in chemotherapy work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Giving hormone therapy together with more than one chemotherapy drug (combination chemotherapy) has been shown to reduce the chance of breast cancer recurrence, but the benefit of adding chemotherapy to hormone therapy for women with node-negative, estrogen-receptor positive breast cancer is small. New tests may provide information about which patients are more likely to benefit from chemotherapy. This randomized phase III trial is trying to find out the best individual therapy for women who have node-negative, estrogen-receptor positive breast cancer by using a special test (Oncotype DX), and whether hormone therapy alone or hormone therapy together with combination chemotherapy is better for women who have an Oncotype DX recurrence score of 11-25.

Eligibility criteria include the following:

- 18-75 years old
- Estrogen receptor (ER)-positive and/or progesterone receptor (PR)-positive tumor
- HER2/neu negative tumor
- Has undergone surgery to remove the tumor within the past 3 months
- No previous chemotherapy or radiation therapy for this cancer
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention:

After surgery, patients will be assigned to one of three treatment groups based on their Oncotype DX recurrence scores.

- **Group one (Oncotype DX recurrence score < 11):** Patients in this group will receive hormone therapy with tamoxifen, anastrozole, letrozole, or exemestane by mouth for up to 5 years. Some patients will then continue to receive hormone therapy for an additional 5 years.
- **Group two (Oncotype DX recurrence score 11-25):** Patients in this group will be randomly assigned (have an equal chance of being placed) to receive either hormone therapy alone or combination chemotherapy and hormone therapy. The patients who receive combination chemotherapy will start receiving hormone therapy no more than 4 weeks after finishing combination chemotherapy. The same hormone therapies used in group one will be used. All patients will receive hormone therapy by mouth for up to 5 or 10 years as in group one.

- **Group three (Oncotype DX recurrence score > 25):** Patients in this group will receive combination chemotherapy followed by hormone therapy similar to the patients in group two who are assigned to receive both types of treatment.

All patients who had breast-conserving surgery also undergo radiation therapy. Some patients complete quality of life assessments periodically. After finishing treatment, patients will be evaluated periodically for up to 20 years.

PENDING APPROVAL

Use of Organic Germanium or Placebo for the Prevention of Radiation Induced Fatigue in Early Stage Breast Cancer

Purpose: Participants will be diagnosed with localized prostate or breast cancer and be scheduled to undergo external beam radiation therapy. Participants will either receive a placebo or organic germanium to be taken 5 times a day starting the day of their first radiation and continuing through the 1 month follow-up visit. Weekly Quality of life forms will be completed through the one month follow up visit and then at the 3 month follow up visit. Labs will be done prior to the start of treatment, at the end of treatment and at the one and three month follow-up visits.

With the increasing public use of complementary medicines, most researchers agree that there is a compelling need to study the safety and efficacy of these agents in humans by means of appropriately designed double-blind, placebo controlled clinical trials. With fatigue affecting 96% of the cancer patient population and little more than life style alterations offered as an intervention, the need to evaluate putative and innovative approaches for fatigue is a high priority. The NIH released a "State of the Science" statement in 2002 which concluded that fatigue is a serious cause of morbidity, being the most prevalent symptom experienced by cancer patients. This expert panel also concluded that the major barrier to effective management of fatigue includes a lack of awareness of this fact, the lack of knowledge of the causes of fatigue, and the lack of proven methods to treat fatigue. Presently, clinical trials evaluating intervention for cancer fatigue are lacking.

Organic germanium literature states that it may be an effective agent for combating fatigue with virtually no toxicities. Since virtually all cancer patients receiving radiation therapy experience fatigue, the use of this drug should be evaluated as an intervention for non-anemic fatigue in breast and prostate cancer patients undergoing a definitive course of radiation therapy. We intend to test whether organic germanium is able to reduce the fatigue experienced by patients undergoing radiation therapy and if this reduction in fatigue correlates to an improvement in quality of life for these patients. Changes in the patients' mood will also be evaluated. We will also collect information on the toxicity profile of Organic germanium and try to determine when the peak fatigue time occurs and possibly when they recover. This information will be utilized to see if a larger study is warranted.

Inclusion Criteria:

1. Histologically-confirmed diagnosis of breast (females only) or prostate cancer
2. Zubrod performance status of 0-1.
3. Patients must be ≥ 18 years of age.
4. Scheduled to undergo definitive radiation therapy (either brachytherapy or external beam)
5. Patients may have received or be receiving hormonal therapy. Prior chemotherapy is allowed as long as the patient has recovered from any toxicity. Planned future chemotherapy is also allowed after the one month evaluation.
6. Hgb ≥ 10 g/dl, BUN < 25 mg and creatinine < 1.5 mg
7. Patient must be able to comply with treatment regimen.
8. Patient must complete the pre-treatment quality of life questionnaires.
9. Women of childbearing potential must have a pre-treatment pregnancy test; women of childbearing potential and men able to father children must use non-hormonal-based birth control while on study.

Exclusion Criteria:

1. Known allergies or reactions to Organic germanium
2. Prior irradiation other than basal cell cancer of skin
3. Current or past history of metastasis
4. Current history of uncontrolled hypertension, insulin dependent or uncontrolled diabetes, cardiovascular disease unless controlled and stable for 6 months or more, bleeding disorders, or autoimmune disorders such as fibromyalgia, chronic fatigue syndrome or lupus
5. Current use of corticosteroids or erythropoietin
6. Patients currently taking Organic germanium, or who have taken Organic germanium within the past three months
7. Pregnant or lactating women, as treatment involves unforeseeable risks to the participant and to the embryo or fetus
8. Patients who are unable to complete quality of life questionnaires
9. Male breast cancer patients

GENITOURINARY CANCER PROTOCOLS

Intermediate Risk Prostate Cancer RTOG 0232

Purpose: Radiation therapy uses high-energy x-rays and other sources to damage tumor cells. Interstitial brachytherapy uses radioactive material placed directly into or near a tumor to kill tumor cells. Combining interstitial brachytherapy with external-beam radiation therapy may kill more tumor cells. It is not yet known whether interstitial brachytherapy is more effective with or without external-beam radiation therapy in treating prostate cancer. This is a randomized phase III trial to compare the effectiveness of interstitial brachytherapy with or without external-beam radiation therapy in treating patients who have prostate cancer.

Eligibility criteria include the following

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- At least 18 years old
- No distant metastases
- No previous chemotherapy
- No previous radiation therapy to the pelvis
- No previous radical surgery for prostate cancer
- No previous cryosurgery or transurethral resection of the prostate
- No previous transurethral needle ablation or microwave thermotherapy of the prostate

Treatment/Intervention: Patients will be randomly assigned to one of two groups.

- Group 1: external-beam radiation therapy 5 days a week for 5 weeks. Two to 4 weeks after completing radiation therapy, they will undergo interstitial brachytherapy.
- Group 2: Patients in group two will undergo interstitial brachytherapy alone.

Quality of life will be assessed periodically. After finishing treatment, patients will be evaluated at 3-5 weeks, 4 and 6 months, every 3 months for 6 months, every 6 months for 4 years, and once a year thereafter.

Ultrasound-Guided Implant Radiation Therapy in Treating Patients With Locally Recurrent Prostate Cancer Previously Treated With External-Beam Radiation Therapy RTOG 0526

Purpose: Implant radiation therapy uses radioactive material placed directly into or near a tumor to kill tumor cells. This phase II trial is studying the side effects and how well ultrasound -guided implant radiation therapy works in treating patients with locally recurrent prostate cancer previously treated with external-beam radiation therapy.

Eligibility criteria include the following:

- At least 18 years old
- Stage I or stage II prostate cancer at diagnosis
- Developed locally recurrent prostate cancer more than 2½ years after finishing external-beam radiation therapy
- Has undergone biopsy of the prostate within the past 6 months
- Prostate-specific antigen (PSA) less than 10 ng/mL
- No lymph node involvement, disease outside the prostate, bone metastases, or other metastatic cancer
- No previous transurethral resection of the prostate, implant radiation therapy to the prostate, surgery to remove the prostate and/or both testicles, or cryosurgery to the prostate
- No previous chemotherapy for prostate cancer
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will undergo ultrasound-guided placement of radioactive implants. Patients will be evaluated every 3 months for 1 year, every 6 months for 4 years, and once a year thereafter.

Prostate Radiation Therapy or Short-Term Androgen Deprivation Therapy and Pelvic Lymph Node Radiation Therapy With or Without Prostate Radiation Therapy in Treating Patients With a Rising PSA After Surgery for Prostate Cancer RTOG 0534

Purpose: Radiation therapy uses high-energy x-rays to kill tumor cells. Androgens can cause the growth of prostate cancer cells. Antihormone therapy, such as flutamide, bicalutamide, and luteinizing hormone-releasing hormone agonist, may lessen the amount of androgens made by the body. It is not yet known which regimen of radiation therapy with or without androgen deprivation therapy is more effective for prostate cancer.

This randomized phase III trial is studying prostate radiation therapy to see how well it works compared with short-term androgen deprivation therapy given together with pelvic lymph node radiation therapy with or without prostate radiation therapy in treating patients with a rising PSA after surgery for prostate cancer.

Eligibility criteria include the following:

- At least 18 years old
- No distant metastases
- No androgen deprivation therapy started before prostatectomy or lasting longer than 6 months
- No androgen deprivation therapy started after prostatectomy
- No previous radiation therapy to the pelvis
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will be randomly assigned (have an equal chance of being placed) to one of three treatment groups.

- Patients in group one will undergo radiation therapy to the prostate 5 days a week for up to 8 weeks.
- Patients in group two will receive flutamide by mouth three times a day or bicalutamide by mouth once a day for at least 4 months. Beginning at the same time or 2 weeks after starting flutamide or bicalutamide, they will receive luteinizing hormone-releasing hormone agonist by injection for up to 6 months. Beginning approximately 2 months after starting flutamide or bicalutamide, patients will undergo radiation therapy to the prostate 5 days a week for up to 8 weeks.
- Patients in group three will receive flutamide or bicalutamide and luteinizing hormone-releasing hormone agonist as in group two. Beginning approximately 2 months after starting flutamide or bicalutamide, patients will undergo radiation therapy to the prostate and lymph nodes in the pelvis 5 days a week for approximately 5 weeks. They will then undergo radiation therapy to the prostate 5 days a week for up to 3 weeks.

Patients will fill out a symptom questionnaire 2 months after beginning treatment, at week 6 of radiation therapy, and periodically after finishing treatment. After finishing treatment, patients will be evaluated every 3 months for 1 year, every 6 months for 4 years, and once a year thereafter.

Radiation Therapy, Androgen Suppression, and Docetaxel in Treating Patients With High-Risk Prostate Cancer Who Have Undergone Radical Prostatectomy RTOG 0621

Purpose: Specialized radiation therapy that delivers a high- dose of radiation directly to the tumor may kill more tumor cells and cause less damage to normal tissue. Androgens can cause the growth of prostate cancer cells. Antihormone therapy, such as leuprolide, goserelin, flutamide, or bicalutamide, may lessen the amount of androgens made by the body. Drugs used in chemotherapy, such as docetaxel, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Giving radiation therapy together with androgen suppression and docetaxel after surgery may kill any tumor cells that remain after surgery.

This phase II trial is studying how well giving radiation therapy together with androgen suppression and docetaxel works in treating patients with high risk prostate cancer who have undergone radical prostatectomy.

Eligibility criteria include the following:

- At least 18 years old
- No more than 1 year since radical prostatectomy
- Prostate-specific antigen (PSA) no more than 0.2 ng/mL
- No bone metastases
- No previous chemotherapy for prostate cancer
- More than 3 years since chemotherapy for any other cancer
- No previous androgen suppression therapy for prostate cancer
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will receive an injection of leuprolide or goserelin. They will also receive flutamide by mouth three times a day or bicalutamide by mouth once a day. Treatment may continue for up to 6 months. Beginning 8 weeks after starting hormone therapy, patients will undergo 3-dimensional conformal radiation therapy or intensity-modulated radiation therapy 5 days a week for up to 8 weeks. Beginning 3-6 weeks after finishing radiation therapy, patients will receive a 1-hour infusion of docetaxel. Treatment may repeat every 3 weeks for up to six courses. After finishing treatment, patients will be evaluated every 3 months for 2 years, every 6 months for 3 years, and once a year thereafter.

Samarium Sm 153 Lexidronam Pentasodium and 3-Dimensional Conformal Radiation Therapy or Intensity-Modulated Radiation Therapy in Treating Patients With Rising Prostate-Specific Antigen Levels After Radical Prostatectomy for Prostate Cancer RTOG 0622

Purpose: Giving samarium Sm 153 lexidronam pentasodium and 3-dimensional (3-D) conformal radiation therapy or intensity-modulated radiation therapy may keep prostate cancer from growing in patients with rising prostate-specific antigen (PSA) levels after radical prostatectomy for prostate cancer. This phase II trial is studying how well samarium Sm 153 lexidronam pentasodium and 3-D conformal radiation therapy or intensity-modulated radiation therapy work in treating patients with rising PSA levels after radical prostatectomy for prostate cancer.

Eligibility criteria include the following:

- At least 18 years old
- Meets 1 of the following criteria:
 - PSA greater than 2.0 ng/mL
 - PSA greater than 0.2 ng/mL and Gleason score 9 or 10
- No distant metastases
- No previous systemic chemotherapy for this cancer
- No hormonal therapy that was started within the past 3 months
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will receive an infusion of samarium Sm 153 lexidronam pentasodium in week 1. Approximately 3 months later, they will undergo 3-D conformal radiation therapy or intensity-modulated radiation therapy 5 days a week for 7-8 weeks. After finishing treatment, patients will be evaluated at 3 months, 6 months, and 12 months, every 6 months for 2 years, and once a year thereafter.

Radiation Therapy With or Without Androgen-Deprivation Therapy in Treating Patients With Prostate Cancer RTOG 0815

Purpose: Radiation therapy uses high-energy x-rays and other types of radiation to kill tumor cells and shrink tumors. Androgens can cause the growth of prostate cancer cells. Androgen-deprivation therapy may lessen the amount of androgens made by the body. It is not yet known whether radiation therapy is more effective with or without androgen-deprivation therapy in treating patients with prostate cancer. This randomized phase III trial is studying radiation therapy to see how well it works compared with radiation therapy given together with androgen-deprivation therapy in treating patients with prostate cancer.

Eligibility criteria include the following:

- At least 18 years old
- No more than 6 months since diagnosis
- No previous prostatectomy, high-intensity focused ultrasound, or cryosurgery for prostate cancer
- No previous goserelin, leuprolide, flutamide, bicalutamide, or DES
- No previous surgery to remove both testicles
- More than 1 month since finasteride
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will be randomly assigned (have an equal chance of being placed) to one of two treatment groups.

- Some patients in group one will undergo external-beam radiation therapy 5 days a week for up to 9 weeks. Other patients will receive implant radiation therapy 5 days a week for approximately 5 weeks.
- Patients in group two will receive an injection of leuprolide, goserelin, buserelin, or triptorelin every 1-3 months and flutamide by mouth three times a day or bicalutamide by mouth once a day for 6 months. Beginning 2 months

after the first injection, they will undergo external-beam radiation therapy 5 days a week for up to 9 weeks or implant radiation therapy 5 days a week for approximately 5 weeks.

After finishing treatment, patients will be evaluated periodically.

Tadalafil in Preventing Erectile Dysfunction in Patients With Prostate Cancer Treated With Radiation Therapy RTOG 0831

Purpose: Tadalafil may help prevent erectile dysfunction in patients with prostate cancer that has been treated with radiation therapy. It is not yet known whether tadalafil is more effective than a placebo in preventing erectile dysfunction. This randomized phase III trial is studying tadalafil to see how well it works compared with a placebo in preventing erectile dysfunction in patients with prostate cancer treated with radiation therapy.

Eligibility criteria include the following:

- At least 18 years old
- No previous penile implant or surgery to remove both testicles
- No previous surgery, cryosurgery, high-intensity focused ultrasound, radionuclide implant, or chemotherapy for prostate cancer
- More than 6 months since leuprolide acetate, goserelin, bicalutamide, flutamide, nilutamide, or diethylstilbestrol
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will be randomly assigned (have an equal chance of being placed) to one of two treatment groups. All patients will undergo external-beam radiation therapy or implant radiation therapy.

- Beginning within 1 week after starting radiation therapy, patients in group one will receive tadalafil by mouth once a day for up to 6 weeks.
- Beginning within 1 week after starting radiation therapy, patients in group two will receive a placebo by mouth once a day for up to 6 weeks.

Patients will fill out questionnaires about erectile function, sexual adjustment, and medications and devices periodically. Partners or spouses will also fill out questionnaires periodically. After finishing treatment, patients will be evaluated at approximately 7 months and once a year for up to 2 years.

CyberKnife Radiosurgery for Organ-Confined Prostate Cancer: Homogenous Dose Distribution

Purpose: The purpose of this study is to determine the effects of CyberKnife radiosurgery in patients with early stage organ-confined prostate cancer. The CyberKnife Robotic Radiosurgery System is a unique radiosurgical system capable of treating tumors anywhere in the body noninvasively and with sub-millimeter accuracy. The CyberKnife System delivers radiation using a precise targeting methodology allowing a focal treatment margin around the target, thus limiting the volume of adjacent tissue receiving high doses radiation. This in turn allows the delivery of high doses of radiation to the prostate over a short series of treatments.

Inclusion Criteria:

- Patient must be at least 18 years of age
- Histologically proven prostate adenocarcinoma
- Patients belonging in one of the following risk groups: Low: CS T1b-T2a and Gleason 2-6 and PSA ≤ 10 , or Intermediate: CS T2b and Gleason 2-6 and PSA ≤ 10 or CS T1b-T2b, and Gleason 2-6 and PSA ≤ 20 ng/ml or Gleason 7 and PSA ≤ 10 ng/ml
- Prostate volume: ≤ 100 cc
- ECOG performance status 0-1

Exclusion Criteria:

- Prior prostatectomy or cryotherapy of the prostate
- Prior radiotherapy to the prostate or lower pelvis
- Implanted hardware or other material that would prohibit appropriate treatment planning or treatment delivery, in the investigator's opinion
- Chemotherapy for a malignancy in the last 5 years
- History of an invasive malignancy (other than this prostate cancer, or basal or squamous skin cancers) in the last 5 years.
- Hormone ablation for two months prior to enrollment, or during treatment.

A COMBINATION OF EXTERNAL BEAM RADIOTHERAPY FOLLOWED BY A CESIUM BRACHYTHERAPY IMPLANT FOR EARLY STAGE PROSTATE CANCER

Purpose: To compare information on how patients are doing over time, side effects from the treatments, and quality of life of patients being treated with brachytherapy with the Cesium seed and external beam radiotherapy. This information will be compared to similar information from the other types of implant seeds available.

Eligibility criteria includes the following: Path-confirmed, locally confined adenocarcinoma of the prostate; Clinical stages T1c-T2c Karnofsky 90 - 100; Age \geq 18 years; Combined Gleason 7 if PSA < 10.1, stage T2a or less; combined Gleason 6 or less if PSA 10.1-20, stage T2a or less; Gleason 6 or less, PSA < 10.1, stage T2b; Any Gleason with PSA > 20 and stage T2c or less; Gleason >7, any PSA, stage T2c or less, Any Gleason, any PSA and Stage T2c. Prostate volume by TRUS \leq 60 cc; No prior chemotherapy, pelvic RT, no prior TURP, cryosurgery, TUNA, TUMT or radical surgery for carcinoma of the prostate; No previous hormonal therapy beginning < 3 months or > 6 months prior to registration; No distant metastases, no clinically or pathologically involved lymph nodes; No significant obstructive symptoms; AUA must be \leq 15 (alpha blockers allowed); No hip prosthesis; No major medical or psychiatric illness. Protocol treatment must begin within 4 weeks after study entry

Treatment/Intervention: 45 Gy EBRT, partial pelvis (1.8 Gy/fraction M-F for 5 weeks) followed 2-4 weeks later by CS131

Use of Organic Germanium or Placebo for the Prevention of Radiation Induced Fatigue in Early Stage Prostate Cancer

Purpose: Participants will be diagnosed with localized prostate or breast cancer and be scheduled to undergo external beam radiation therapy. Participants will either receive a placebo or organic germanium to be taken 5 times a day starting the day of their first radiation and continuing through the 1 month follow-up visit. Weekly Quality of life forms will be completed through the one month follow up visit and then at the 3 month follow up visit. Labs will be done prior to the start of treatment, at the end of treatment and at the one and three month follow-up visits.

With the increasing public use of complementary medicines, most researchers agree that there is a compelling need to study the safety and efficacy of these agents in humans by means of appropriately designed double-blind, placebo controlled clinical trials. With fatigue affecting 96% of the cancer patient population and little more than life style alterations offered as an intervention, the need to evaluate putative and innovative approaches for fatigue is a high priority. The NIH released a "State of the Science" statement in 2002 which concluded that fatigue is a serious cause of morbidity, being the most prevalent symptom experienced by cancer patients. This expert panel also concluded that the major barrier to effective management of fatigue includes a lack of awareness of this fact, the lack of knowledge of the causes of fatigue, and the lack of proven methods to treat fatigue. Presently, clinical trials evaluating intervention for cancer fatigue are lacking.

Organic germanium literature states that it may be an effective agent for combating fatigue with virtually no toxicities. Since virtually all cancer patients receiving radiation therapy experience fatigue, the use of this drug should be evaluated as an intervention for non-anemic fatigue in breast and prostate cancer patients undergoing a definitive course of radiation therapy. We intend to test whether organic germanium is able to reduce the fatigue experienced by patients undergoing radiation therapy and if this reduction in fatigue correlates to an improvement in quality of life for these patients. Changes in the patients' mood will also be evaluated. We will also collect information on the toxicity profile of Organic germanium and try to determine when the peak fatigue time occurs and possibly when they recover. This information will be utilized to see if a larger study is warranted.

Inclusion Criteria:

1. Histologically-confirmed diagnosis of breast (females only) or prostate cancer
2. Zubrod performance status of 0-1.
3. Patients must be \geq 18 years of age.
4. Scheduled to undergo definitive radiation therapy (either brachytherapy or external beam)
5. Patients may have received or be receiving hormonal therapy. Prior chemotherapy is allowed as long as the patient has recovered from any toxicity. Planned future chemotherapy is also allowed after the one month evaluation.
6. Hgb \geq 10 g/dl, BUN < 25 mg and creatinine < 1.5 mg
7. Patient must be able to comply with treatment regimen.
8. Patient must complete the pre-treatment quality of life questionnaires.

9. Women of childbearing potential must have a pre-treatment pregnancy test; women of childbearing potential and men able to father children must use non-hormonal-based birth control while on study.

Exclusion Criteria:

1. Known allergies or reactions to Organic germanium
2. Prior irradiation other than basal cell cancer of skin
3. Current or past history of metastasis
4. Current history of uncontrolled hypertension, insulin dependent or uncontrolled diabetes, cardiovascular disease unless controlled and stable for 6 months or more, bleeding disorders, or autoimmune disorders such as fibromyalgia, chronic fatigue syndrome or lupus
5. Current use of corticosteroids or erythropoietin
6. Patients currently taking Organic germanium, or who have taken Organic germanium within the past three months
7. Pregnant or lactating women, as treatment involves unforeseeable risks to the participant and to the embryo or fetus
8. Patients who are unable to complete quality of life questionnaires
9. Male breast cancer patients

TARGETED, TAILORED AND TIMELY (T3) SYMPTOM MANAGEMENT FOR PROSTATE CANCER

Purpose: To test how different learning methods can help gentleman with prostate cancer manage any side effects as a result of their radiation therapy.

Eligibility Criteria include the following: Participants must have biopsy confirmed prostate cancer, be over the age of 65 and be in the process of receiving radiation therapy. In order to offered entry into the study, the gentleman must have received 4 weeks of radiation therapy and be experiencing problems with urination and/or bowels. They will then be offered the study. The men that take part must be able to take care of themselves, not have a hearing impairment and be able to read and speak English (due to the tools used in the study).

Treatment/Intervention: The participants will be placed into one of two groups. Group 1 will receive care that they would have received if they were not enrolled in the study. Group two will receive additional intervention by one of three methods, either learning on your own and an email address for questions, a weekly phone conference or one to one time with a nurse once a week. Any of the coordinators can consent the patient and Norissa will be the nurse performing the interventions. We are working with the University of Utah and Huntsman Cancer Center on this project with funding from an RO1 grant.

HEAD and NECK CANCER PROTOCOLS

PROSPECTIVE, LONGITUDINAL, MULTI-CENTER, DESCRIPTIVE REGISTRY OF PATIENTS RECEIVING THERAPY OTHER THAN SURGICAL RESECTION ALONE FOR NEWLY DIAGNOSED HEAD AND NECK CARCINOMA (LORHAN).

Purpose: This registry study of over 11, 000 patients is being done to collect information to develop new standard treatments and also to see if there is a difference between the community doctors and University based doctors. The study will also collect information to see what the different treatments do to the tumors and see if they can prevent the tumors from coming back. Information on side effects and medication use will also be collected.

Eligibility criteria include the following: Any patient that is going to receive radiation therapy as part of their care for their newly diagnosed cancer of the head and neck areas can take part in this registry study as long as they are over the age of 18.

Treatment/Intervention: There is no specific treatment for this study. The study just allows us to collect the information on the treatment the patient is receiving. We meet with the patient before the start of their treatment, at the end of their treatment, the 1 month follow-up visit and at least once a year afterwards.

LUNG CANCER PROTOCOLS

Stereotactic Body Radiation Therapy in Treating Patients With Stage I or Stage II Non-Small Cell Lung Cancer That Can Be Removed By Surgery RTOG 0618

Purpose: Stereotactic body radiation therapy may be able to send x-rays directly to the tumor and cause less damage to normal tissue near the tumor. This phase II trial is studying how well stereotactic body radiation therapy works in treating patients with stage I or stage II non-small cell lung cancer that can be removed by surgery.

Eligibility criteria include the following:

- At least 18 years old
- No regional metastases or distant metastases
- No previous radiation therapy, chemotherapy, or surgery for lung cancer
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will undergo three stereotactic body radiation therapy treatments over 2 weeks. Some patients will then undergo surgery to remove the tumor. After finishing treatment, patients will be evaluated periodically for up to 5 years.

PENDING - Submitted to IRB and awaiting credentialing

Stereotactic Body Radiation Therapy in Treating Patients With Stage I Non-Small Cell Lung Cancer RTOG 0813

Purpose: Stereotactic body radiation therapy may be able to send x-rays directly to the tumor and cause less damage to normal tissue. This phase I/II trial is studying the side effects and best dose of stereotactic body radiation therapy and to see how well it works in treating patients with stage I non-small cell lung cancer.

Eligibility criteria include the following:

- At least 18 years old
- Not able to undergo surgery
- Measurable disease
- No previous chemotherapy for this cancer
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will undergo stereotactic body radiation therapy every 2 days for up to 2 weeks. After finishing treatment, patients will be evaluated periodically.

PENDING - Submitted to IRB and awaiting credentialing

Radiation Therapy in Treating Patients With Stage I Non-Small Cell Lung Cancer RTOG 0915

Purpose: Radiation therapy uses high-energy x-rays to kill tumor cells. Specialized radiation therapy that delivers a high dose of radiation directly to the tumor may kill more tumor cells and cause less damage to normal tissue. It is not yet known which regimen of stereotactic body radiation therapy is more effective in treating patients with non-small cell lung cancer. This randomized phase II trial is studying the side effects of two radiation therapy regimens and to see how well they work in treating patients with stage I non-small cell lung cancer.

Eligibility criteria include the following:

- At least 18 years old
- No metastatic cancer
- Measurable disease
- No previous radiation therapy to the lung or chest
- No previous chemotherapy or surgery for tumors in the lung or chest
- For more information about the eligibility criteria for this trial, refer to the Health Professional version.

Treatment/Intervention: Patients will be randomly assigned (have an equal chance of being placed) to one of two treatment groups.

- Patients in group one will undergo radiation therapy once.
- Patients in group two will undergo radiation therapy once a day for 4 days.

Patients will undergo blood and tumor tissue sample collection for laboratory studies. After finishing treatment, patients will be evaluated every 3 months for 2 years, every 6 months for 2 years, and once a year thereafter.

PENDING - Submitted to IRB and awaiting credentialing

CyberKnife Radiosurgical Treatment of Inoperable Early Stage Non-Small Cell Cancer

Purpose: To assess the short and long-term outcomes after CyberKnife stereotactic radiosurgery for early stage non-small cell lung cancer (NSCLC) in patients who are medically inoperable.

Inclusion Criteria:

- Patient must be over the age of 18 years
- Histological confirmation of primary NSCLC
- Pulmonary nodule size less than or equal to 5 cm
- The following stage of NSCLC patients are eligible:
- Stage I: T1, N0, M0 or T2, N0, M0 (Tumor size \leq 5cm)
- Stage II: T3, N0, M0 (Chest wall invasion only, Tumor size \leq 5cm)
- ECOG/Zubrod status of 0, 1, or 2
- In order to be considered medically inoperable, the patient must meet at least one major criteria or a minimum of 2 criteria as described below:

MAJOR CRITERIA:

- FEV1 $<$ 50% or predicted postoperative FEV1 $<$ 40%
- DLCO $<$ 50% or predicted postoperative DLCO $<$ 40%
- Exercise induced maximal exercise oxygen consumption ($M\ VO_2$) $<$ 15/kg/min
- Thoracic surgery consultation should be obtained from a Board Certified Thoracic Surgeon who in collaboration with a Radiation Oncologist should determine that the patient is not a surgical candidate.

MINOR CRITERIA:

- Age $>$ 80 years
- Pulmonary hypertension (defined as a pulmonary artery systolic pressure $>$ than 40 mm Hg)
- Oxygen requirement
- Congestive heart failure (any 3 of the following must be documented: dyspnea, peripheral edema, chest x-ray with interstitial edema or cardiomegaly, rales or congestion)
- Poor left ventricular function (defined as an ejection fraction of 40% or less)
- Severe cerebral (with CVA or recent TIA) or severe peripheral vascular disease
- Diabetes Mellitus with severe organ damage
- Females of child bearing age must be using a reliable form of birth control
- PET-CT scan completed within 6 weeks of registration

Exclusion Criteria:

- Prior history of cancer within the last 5 years or concurrent cancer other than basal cell or squamous cell carcinoma
- Weight exceeds the tolerances of the institution's imaging and CyberKnife platform/couch
- Thoracic radiation therapy in the same field as the planned treatment area
- Patient has completed chemotherapy within less than 30 days of treatment
- Stage T2 with tumor size $>$ 5 cm; Stage T3 (except T3 chest wall invasion only and \leq 5 cm); Stage T4
- Presence of N1, N2 or N3 disease
- Pancoast tumors
- Current distant metastases (M1)
- Female with child-bearing potential who refuses to take a pregnancy test prior to treatment
- Pregnant or nursing female
- Active systemic or pulmonary infection
- Undergoing systemic therapy within 2 weeks after last fraction of radiation

International Randomized Study to Compare CyberKnife Stereotactic Radiotherapy With Surgical Resection In Stage I Non-small Cell Lung Cancer (STARS)

Purpose: Lung cancer remains the most frequent cause of cancer death in both men and women in the world. Surgical resection using lobectomy with mediastinal lymph node dissection or sampling has been a standard of care for operable early stage NSCLC. Several studies have reported high local control and survival using SBRT in stage I NSCLC patients. SBRT is now an accepted treatment for medically inoperable patients with stage I NSCLC and patients with operable stage I lung cancer are entered on clinical protocols. The purpose of this study is to conduct a phase III randomized study to compare CyberKnife SBRT with surgery, the current standard of care for stage I operable NSCLC.

Primary Goal: To compare overall survival at 3 years.

Secondary goals:

1. To compare disease specific survival at 3 years.
2. To compare 3 year progression free survival at the treated primary tumor site
3. To compare grade 3 and above acute and/or chronic toxicities.
4. To evaluate predictive value of pre and post treatment PET scan in clinical outcome.

Inclusion Criteria:

1. Histological confirmation of non-small cell cancer will be required by either biopsy or cytology. The following primary cancer types are eligible: squamous cell carcinoma, adenocarcinoma with or without BAC features, large cell carcinoma with or without neuroendocrine features, neuroendocrine carcinoma, bronchioloalveolar cell carcinoma, or non-small cell carcinoma not otherwise specified.
2. T1, N0, M0 or T2 (<4 cm), N0, M0
3. A PET/CT scan is required. Patients with hilar or mediastinal lymph nodes with short axis diameter < 1cm and no abnormal hilar or mediastinal uptake on PET will be considered N0. Patients with > 1 cm short axis diameter of hilar or mediastinal lymph nodes on CT or abnormal PET (including suspicious but non-diagnostic uptake) may still be eligible if directed tissue biopsy of all abnormally identified areas are negative for cancer. Solitary pulmonary lesions <4mm will not be considered significant.
4. The patients must be considered a reasonable candidate for surgical resection of the primary tumor. Standard justification for deeming a patient medically operable based on pulmonary function for surgical resection of NSCLC may include any of the following: Baseline FEV1 > 40% predicted, post-operative predicted FEV1 > 30% predicted, diffusion capacity > 40% predicted, absent baseline hypoxemia and/or hypercapnia, exercise oxygen consumption > 50% predicted, absent severe pulmonary hypertension, absent severe cerebral, cardiac, or peripheral vascular disease, and absent severe chronic heart disease.
5. Patients must be ≥ 18 years of age.
6. The patient's Zubrod performance status must be Zubrod 0-2.
7. Mandatory staging studies: Must be done within 8 weeks prior to study entry
8. Patients must sign a study-specific consent form.
9. Patients (men and women) of child bearing potential should use an effective (for them) method of birth control throughout their participation in this study.

Exclusion Criteria:

1. Patients with primary tumors > 4 cm;
2. Direct evidence of regional or distant metastases after appropriate staging studies, or synchronous primary or prior malignancy in the past 5 years other than nonmelanomatous skin cancer or in situ cancer;
3. Previous lung or mediastinal radiotherapy;
4. Plans for the patient to receive other concomitant local therapy (including standard fractionated radiotherapy and surgery) while on this protocol except at disease progression;
5. Pregnant or lactating women, as treatment involves unforeseeable risks to the embryo or fetus;
6. Can not achieve acceptable SRT planning to meet minimal requirement of target coverage and dose-volume constraints of critical structures (see RT techniques).

MISC PROTOCOLS

Efficiency of Screening for Depression in Cancer Patients Receiving Radiotherapy RTOG 0841

Purpose: To test the use of a centralized screening procedure for major depression in cancer patients receiving radiotherapy at multiple treatment centers. The study will also be able to find out if the current rate of depression in cancer patients is correct. Patients that agree to the study will complete some questionnaires. These questionnaires will be sent to the University of Pennsylvania to be reviewed. If the patient is found to have major depression symptoms, they will be offered help by qualified people, either through the study or through local professionals.

Eligibility criteria include the following:

- Patient is undergoing radiation treatment for their first diagnosis of cancer
- Patient is at least 21 years of age
- No mental incompetence which would preclude completion of questionnaires.
- Patient is not considered suicidal or psychotic or otherwise unfit for study participation.

