ONGOING CLINICAL PROTOCOLS AT OCHSNER

Brain Cancer

Sponsor: Radiation Treatment Oncology Group, National Cancer Institute

Investigator: ---------- Troy Scroggins, MD

Contact: Alice Prososki, RN 504-842-3708

Title:
A phase III study of conventional radiation therapy plus thalidomide versus conventional radiation therapy for multiple brain metastases.

Study Objective:
The purpose of this study is to compare overall survival of patients treated with orally administered thalidomide starting concomitantly with conventional radiation therapy to radiation therapy alone.

Inclusion Criteria:
- Extracranial primary malignancy
- Multiple brain metastases, or one lesion > 4.0 cm in diameter or metastatic to mid brain or brainstem
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Exclusion Criteria:
- Grade 2 sensory neuropathy
- Chemotherapy within 2 weeks of study entry
- Previous head or neck radiotherapy
- Previous radiosurgery
- Prior thalidomide treatment

Products and/or services supplied to study participants:
The study drug is provided free of charge.

Breast Cancer Prevention

Sponsor: National Surgical Adjuvant Breast and Bowel Project, National Cancer Institute

Investigator: ---------- Carl G, Kardinal, MD

Contact: Daphne Caldwell, RN 504-842-3708

Title:
A clinical trial comparing anastrozole with tamoxifen in postmenopausal patients with ductal carcinoma in situ (DCIS) undergoing lumpectomy with radiation therapy.

Study Objective:
The primary aim of this study is to compare the value of anastrozole to tamoxifen, each given for 5 years, in preventing the subsequent ocurrence of breast cancer following lumpectomy with radiation therapy in postmenopausal women with DCIS.

Inclusion Criteria:
- DCIS removed by lumpectomy with free margins
- ER-positive or PgR-positive by IHC
- Postmenopausal
- Within 84 days of last surgery

Exclusion Criteria:
- Invasive or microinvasive breast cancer
- DCIS removed by mastectomy
- Current Coumadin therapy
- Previous or current aromatase inhibitors or tamoxifen
- History of DVT, PE, TIA, or CVA

Products and/or services supplied to study participants:
The study drug is provided free of charge.

Breast Cancer Prevention

Sponsor: National Surgical Adjuvant Breast and Bowel Project, National Cancer Institute

Investigator: ---------- Carl G. Kardinal, MD

Contact: Carrie Silverman, RN, BSN 504-842-3708

Title:
STAR trial: the study of tamoxifen and raloxifene in the prevention of breast cancer in high-risk women.

Study Objective:
The primary aim of this study is to determine if raloxifene is as good as tamoxifen in preventing breast cancer in high-risk women.

Inclusion Criteria:
- Postmenopausal women over 34 years of age
- At increased risk of breast cancer

Exclusion Criteria:
- Prior invasive breast cancer or DCIS, or LCIS treated with mastectomy, radiation or systemic therapy
- Bilateral or unilateral prophylactic mastectomy
- Current hormone replacement therapy, Coumadin, or cholestyramine
- Previous tamoxifen, raloxifene, or other SERM for >3 months

Products and/or services supplied to study participants:
The study drug is provided free of charge.

Colorectal Cancer Metastatic to the Liver

Sponsor: North Central Cancer Treatment Group, National Cancer Institute

Investigator: ---------- John Bolton, MD

Contact: Faith Seay, RN 504-842-3708

Title:
A phase II trial evaluating multiple metastectomy combined with hepatic artery infusion of floxuridine and dexamethasone (DXM) alternating with systemic oxaliplatin and capecitabine for colorectal carcinoma metastatic to the liver.

Study Objective:
This study is being done to assess the safety of oxaliplatin/capecitabine in combination with hepatic artery infusion and to assess the 2-year survival rate in patients having initiated hepatic artery infusion of floxuridine/dexamethasone combined with systemic oxaliplatin/capecitabine following complete resection of hepatic metastases.

Inclusion Criteria:
- Adequate oral intake
- Ability to withstand major operative procedure
- No more than one prior surgical adjuvant systemic 5-FU therapy with or without any combination of levamisole, leucovorin, or CPT-11
- Prior history of colon or rectal carcinoma completely resected
- Adequate laboratory values

Exclusion Criteria:
- Chronic hepatic disease
- Prior hepatic artery infusion with 5-FU or FUDR or any systemic chemotherapy for metastatic disease
- Extrahepatic metastases evident on preoperative work-up

Products and/or services supplied to study participants:
Oxaliplatin and capecitabine provided free of charge. Infusion pump provided if not covered by subject's insurance.

Colorectal Cancer Screening

Sponsor: North Central Cancer Treatment Group, National Cancer Institute

Investigator: ---------- *Carl G. Kardinal, MD*

Contact: Carrie Silverman, RN, BSN 504-842-3708

Title:
Colorectal cancer screening: fecal blood vs. DNA.

Study Objective:
The purpose of this study is to:
- Compare two stool tests, a multitarget DNA-based assay panel and Hemoccult, against colonoscopy for their use as a screening tool for the detection of colon polyps and colon cancer
- Explore the possibility of using a blood test as a screening tool for colon polyps and colon cancer
- Investigate the possibility of finding other cancers above the colon

Inclusion Criteria:
- Between the ages of 50 and 80 years
- Female patients must be postmenopausal

Exclusion Criteria:
- Fecal occult blood test screening in the past year
- Structural colorectal cancer evaluation in the past 10 years
- High-risk for colon cancer
- Inability to stop therapeutic NSAIDs
- Anticoagulant use

Non-Small-Cell Lung Cancer

Sponsor: Eastern Cooperative Cancer Group, National Cancer Institute

Investigator: ---------- Carl G. Kardinal, MD

Contact: DeDe Keller, RN, BSN 504-842-3708

Title:
A phase III prospective, randomized, double-blind, placebo-controlled trial of the epidermal growth factor receptor agonist ZD1839 (IRESSA) in completely resected primary stage IB, II, IIIA non-small-cell lung cancer.

Study Objective:
The purpose of this study is to assess, in comparison with placebo, the impact of adjuvant therapy with 2 years of daily oral ZD1839 (IRESSA) on the overall survival of patients with completely resected (T1N1-2, T2N0-2, T3N0-2) non-small-cell lung cancer.

Inclusion Criteria:
- Classified postoperatively as stage IB, II, or IIIA on the basis of pathologic criteria
- Surgery may consist of lobectomy, sleeve resection, bilbectomy, or pneumonectomy
- All gross disease must have been resected
- Negative surgical margins
- No more than 16 weeks from surgery

Exclusion Criteria:
- Prior or concurrent malignancy
- Combination of small-cell and non-small-cell carcinomas or pulmonary carcinoid tumor
- More than one discrete area of apparent primary cancer
- Prior or concurrent chemotherapy (however, may have received preoperative, limited-field, external beam radiation therapy)

Products and/or services supplied to study participants:
The study drug is provided free of charge.

Prostate Cancer Prevention

Sponsor: Southwest Oncology Group, National Cancer Institute

Investigator: ---------- Stephen Bardot, MD

Contact: Maria McNeely, RN, BSN 504-842-3115

Title:
SELECT: selenium and vitamin E cancer prevention trial.

Study Objective:
The primary objective of this study is to assess the effect of selenium and vitamin E on the incidence of prostate cancer diagnosed during routine clinical practice.

Inclusion Criteria:
- Male age 55 years or older (50 or older for African American men)
- Nonsuspicious DRE
- Total PSA < 4.0 ng/mL

Exclusion Criteria:
- Previous malignancy
- History of hemorrhagic stroke
- Current selenium or vitamin E

Products and/or services supplied to study participants:
The study drug is provided free of charge.

Lung Cancer Screening

Sponsor: National Cancer Institute

Investigator: ---------- Dr Michael Sullivan

Contact: Lisa Pineda (504) 842- LUNG (5864) or Pamela Dow at (504) 842-6487

Title:
SELECT: Contemporary Screening for the Detection of Lung Cancer.

Study Objective:
Compare spiral CT and chest radiograph for early detection of lung cancer in smokers and former smokers ages 55-74 yrs. Objective is to discover an effective screening test for early lung cancer while it is treatable, and to reduce morbidity and mortality rates associated with lung cancer.

Inclusion Criteria:
- Smokers or former smokers with 30 pack/year history (former smokers within 15 years) No recent history of cancer within past 5 years
- Ages 55-74 years
- No prior history of lung cancer

Products and/or services supplied to study participants:
No cost annual screening for 3 years via chest radiograph or spiral CT.