Ongoing Clinical Protocols at Ochsner

The trials listed here represent just a few examples of Ochsner Clinic Foundation's ongoing research into the causes, diagnoses, and treatments of colon and rectal cancer. If you have patients meeting the listed criteria for a given trial, please call the contact numbers for more information on enrollment. For more information about Ochsner's research programs, please call Ochsner Research Administration at 504 842-3265.

Advanced Metastatic Colorectal Cancer

Sponsor: Bayer
Investigator: Carl G. Kardinal, MD 504 842-3708
Alice Prososki 504 842-3708

Title:
Single agent BAY 56-37222, uncontrolled phase II study, in patients with advanced or metastatic colorectal cancer, who are considered resistant/refractory to irinotecan.

Study Objective:
This is a multicenter, noncomparative, phase II study evaluating the antitumor activity, safety, quality of life, and tolerabiliy of BAY 56-3722 in patients with locally advanced or metastatic refractory colorectal carcinoma. Patients will receive BAY 56-3722 IV over 30 minutes for 3 days. Treatment cycles will be repeated every 3 weeks until there is objective evidence of tumor progression, unacceptable toxicity, consent is withdrawn, or until the investigator deems that continuation of treatment adds no more benefit for the patient.

Inclusion Criteria
Patients must have documented evidence of cancer within the last 6 months and documented progression while on ironotecan or within 6 months after treatment. The patient must be at least 18 years old, have an ECOG performance of 2 or less, and have measurable disease by CT or MRI. Prior surgery, immunotherapy, or irradiation is permited.

Exclusion Criteria
Patients with cliinically evident CHF, severe arrythmias, coronary heart disease, or ischemia on previous stress tests are not eligible. No patient with active infection or with a history of HIV, chronic hepatitis B or C will be eligible. Patients with metastatic brain lesions, untreated or treated in the previous 6 months are ineligible. Those with chronic diarrhea or unresolved bowel obstruction are ineligible. Bulky disease (>50% liver involvement, > 25% lung involvement, or abdominal mass >/= 10 cm) is also an exclusion.

Stage II and III Colon Cancer

Sponsor: National Surgical Adjuvant Breast and Bowel Project
Investigator: Carl Kardinal, MD 504 842-3708
Faith Seay, RN, BSN 504 842-3708

Title:
NSABP C-07: A clinical trial comparing 5-fluorouracil (5-FU) plus leucovorin (LV) and oxaliplatin with 5-FU plus LV for the treatment of patients with stages II and III carcinoma of the colon.

Study Objective:
The primary aim of this study is to compare the effectiveness of 5-fluorouracil (5-FU), leucovorin (LV), and oxaliplatin with that of 5-FU and LV in patients who have undergone a potentially curative resection of a stage II or III carcinoma of the colon.

Inclusion Criteria
All patients who have had surgery for a potentially curable stage II or III carcinoma of the colon will be considered for entry to this study. The interval beween curative resection and randomization must be no more than 42 days. The distal extent of the tumor must be >/= 12 cm from the anal verge on endoscopy. Postoperative AGC and platelets must be adequate. There must be postoperative evidence of adequate hepatic and renal function.

Exclusion Criteria
Some conditions for patient ineligibility include the following:

- Prior invasive colon or rectal malignancy
- Tumors that demonstrate free perforation
- Pregnancy or lactation
- Noncurative surgical resection or prior chemotherapy or radiotherapy for this malignancy
- Clinical significant peripheral neuropathy

Oxaliplatin is provided free of charge to study subjects.

Colorectal Cancer Screening

Sponsor: North Central Cancer Treatment Group
Investigator: Carl G. Kardinal, MD 504 842-3708
Carrie Silverman, RN, BSN 504 842-3708

Title:
MC9944: Colorectal cancer screening–fecal blood vs. DNA.

Study Objectives:
1. To compare two stool tests (a multi-target DNA-based assay panel and hemoccult) against a colonoscopy for their use as a screening tool in the detection of colon polyps and colon cancers.
2. To explore the possibility of using a blood test as a screening tool for colon polyps and colon cancers.
3. To investigate the possibility of finding other cancers above the colon.

Inclusion Criteria
- Patients between 50 and 80 years of age
- Females must be postmenopausal

Exclusion Criteria
- No FOBT screening in the previous 3 years
- No structural colorectal evaluation in the past 10 years
- High conditions for colon cancer
- Inability to stop therapeutic doses of NSAIDS
- Anticoagulant use

Participants will be billed for routine clinical cost. The aerodigestive work-up performed to rule out cancer (for those participants who have a negative colonoscopy and a positive DNA) is paid for by the study and could include a CT scan, EGD, and a small bowel x-ray.

Colorectal Carcinoma Metastatic to the Liver

Sponsor: North Central Cancer Treatment Group
Investigator: John Bolton, MD 504 842-3708
Faith Seay, RN, BSN 504 842-3708

Title:
N9945: A phase II trial evaluating multiple metastasectomy combined with hepatic artery infusion of floxuridine and dexamethasone alternating with systemic oxaliplatin and capecitabine for colorectal carcinoma metastatic to the liver.

Study Objectives:
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 intiated 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 history of laboratory values

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

Oxaliplatin and capecitabine will be provided free of charge. Infusion pump will be provided if not covered by the participant's insurance company.