Cholangiocarcinoma Clinical Trials – Now Enrolling

It is not the intention of the Cholangiocarcinoma Foundation to provide specific medical advice. We provide website users with information to help them better understand their health conditions and the current approaches related to prevention, diagnosis, treatment and supportive care. *You are urged to always seek the advice of your physician or other qualified healthcare provider.*

STUDY NAME: Study of Low-Dose Radiation Therapy to the Whole Liver in Combination with Gemcitabine and Cisplatin in Intrahepatic Cholangiocarcinoma
ClinicalTrials.gov Identifier: NCT02254681

STUDY CENTER

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OVERVIEW

In this Phase II study, researchers want to determine whether lower dose radiation therapy improves the response derived from chemotherapy for intrahepatic cholangiocarcinoma by combining chemotherapy treatment with low dose radiation therapy to the entire liver and adjacent lymph nodes. Patients with surgically treatable or untreatable disease, and those with disease confined to or outside the liver are eligible for this study. Patients will have 4 cycles of treatment with each cycle lasting 3 weeks. All patients receive the same treatment. Medical history, physical examination and bloodwork are required.
Enrollment: 45 patients
Study Start Date: 9/25/2014
Estimated Study Completion Date: 01/30/2020

PURPOSE OF THE STUDY

1. Determine if the combination of low-dose radiation and chemotherapy results in a better treatment response and longer duration of response compared to that observed with chemotherapy alone

2. Determine if the safety of combined low-dose radiation therapy and chemotherapy treatment is substantially different from that of chemotherapy alone

3. Determine if low-dose radiotherapy alters the safety of liver surgery for those patients who are candidates for surgery after combined low-dose radiation therapy and chemotherapy treatment

INCLUSION CRITERIA – Patients must:

1. Have satisfactory heart, lung, and kidney functions to tolerate chemotherapy treatment, and

2. Have satisfactory blood test results, and

3. Be either fully active or able to walk with assistance

EXCLUSION CRITERIA – Patients must:

1. **NOT** have had prior chemotherapy, surgery, or radiation for intrahepatic cholangiocarcinoma

2. **NOT** have had prior or current diagnoses of cirrhosis, primary sclerosing cholangitis hepatitis viral infections

3. **NOT** be pregnant or unwilling to use adequate contraception (women)

REQUIRED TESTS PRIOR TO BEGINNING STUDY TREATMENT

1. MRI of the abdomen

2. CT scan of the chest

3. Basic laboratory work

POTENTIAL SIDE-EFFECTS

1. **Gemcitabine:** Flu-like symptoms such as fever, fatigue, muscle aches, headache, cough, and mild nausea/vomiting are common. If a decrease in blood counts occur—the dose of chemotherapy will be adjusted in these cases.

2. **Cisplatin:** Flu-like symptoms such as fever, fatigue, muscle aches, headache, cough, and mild nausea/vomiting are common. A decrease in kidney function may occur—giving fluids and reducing in the dose of chemotherapy usually corrects this problem.

3. **Radiation:** Injury to surrounding structures such as stomach, small intestine, kidney, and spinal cord is possible. However, due to precise direction of the radiation combined with the very low doses used in this study, the likelihood of these side effects are low.

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