Multicenter, Open-label, Randomized, Controlled Phase III Clinical Study of the Efficacy and Safety of Photodynamic Therapy Using Porfimer Sodium for Injection as Treatment for Unresectable Advanced Perihilar Cholangiocarcinoma

Clinicaltrials.gov Identifier: NCT02082522

Study Centers:
A total of 40 centers in North America, Europe and Asia will participate. Please see ClinicalTrials.gov as sites are added.

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Overview:
This research study will evaluate the efficacy and safety of Photodynamic Therapy with porfimer sodium administered with Standard Medical Care (SMC) compared to SMC alone on the overall survival time of patients with non-operable advanced cholangiocarcinoma, a rare cancer of the bile ducts.

Photodynamic therapy (PDT) is a combination of a drug, porfimer sodium (Photofrin), which is activated by a light from a laser that emits no heat. The activation of the drug is done by lighting the abnormal areas using a fiber optic device (very fine fiber like a fishing line that permits light transmission) inserted into a flexible tube with a light called cholangioscope for the bile duct. The light will activate the porfimer sodium concentrated in the abnormal tissue, leading to its destruction.

Enrollment: 200 patients across North America, Europe and Asia.
**Study Start Date:** August 2014  
**Estimated Study Completion Date:** December 2018

**Purpose of the Study:**  
To evaluate the safety and efficacy of photodynamic therapy in advanced nonoperable bile duct cancer.

**Required Tests:**  
Endoscopic evaluation of the bile duct, CT scan and lab tests.

**Potential Side Effects:**  
Sensitivity to natural light, temporary inflammation at site of treatment, other typical complications associated with endoscopic evaluation of the bile duct.

**Inclusion Criteria:**
- Males or females aged 18 or older
- Diagnosed with radiologically and biopsy or cytology confirmed inoperable perihilar cholangiocarcinoma Bismuth Tumor Stage III/IV
- Non-menopausal or non-sterile female subjects of childbearing potential must have a negative serum beta-HCG and use a medically acceptable form of birth control
- Able to sign an informed consent

**Exclusion Criteria:**
- Diagnostic of cholangiocarcinoma made more than 45 days prior to randomization
- Cholangiocarcinoma with extra-hepatic metastasis or concurrent non-solid malignancy
- Presence or history of other neoplasms (treated during the last five years prior to study entry) other than carcinoma in situ of the cervix or basal carcinoma of the skin
- Previously received photodynamic therapy for cholangiocarcinoma
- Previously undergone surgical resection of the cholangiocarcinoma
- Previously undergone chemotherapy, brachytherapy, or radiotherapy prior to
• Entering the study
• Previously undergone metal stent insertion
• Porphyria or hypersensitivity to porphyrins (constituents of porfimer sodium), gemcitabine, cisplatin or other platinum-containing compounds
• Presence of infection other than the infection of the bile duct (cholangitis)
• Acute or chronic medical or psychological illnesses that prevent endoscopy procedures
• Abnormal blood test results
• Severe impairment of your kidney or liver function
• Decompensated cirrhosis
• Pregnant or intend to become pregnant, breastfeeding or intend to breast-feed during this study
• Participated in another drug study within 90 days before this one
• Unable or unwilling to complete the follow-up evaluations required for the study