S0809 Phase II

Coordinating Group: SWOG

A Phase II Trial of Adjuvant Capecitabine/Gemcitabine Chemotherapy Followed by Concurrent Capecitabine and Radiotherapy in Extrahepatic Cholangiocarcinoma (EHCC)

Participants: SWOG, CTSU (endorsed by ACOSOG, NCCTG and RTOG)

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Objectives
To estimate the stratum-specific (R0 and R1) and overall two-year survival probabilities of EHCC patients treated with adjuvant capecitabine/gemcitabine followed by capecitabine and radiotherapy.

To estimate the two-year stratum-specific and overall disease-free survival and local disease-free survival attained with this regimen.

To assess the frequency and severity of toxicities associated with this regimen.

Patient Population
Patients must have a histopathological diagnosis of extrahepatic cholangiocarcinoma (gall bladder or bile duct) and must not have ampullary cancer. Patients must have pathological T2-4 disease, pathological N1 disease, or positive margins. Patients with distantly metastatic disease are not eligible; however positive resected regional lymph nodes are allowed.

Patients must have received a potentially curative radical resection with negative (R0) or microscopically positive (R1) margins. Prior chemotherapy or radiation therapy is allowed; however patients must not have received previous upper abdominal radiation therapy.

Patients must have adequate hematologic, renal and hepatic function, as well as a Zubrod performance status of 0 or 1. Specimens must be available to be submitted for pathology review. Sites must seek additional patient consent for the use of tissue for future research.

Stratification/Descriptive Factors
Patients will be stratified by margin of resection: negative (R0) vs microscopically positive (R1).

Accrual Goals
A total of 80 patients will be accrued, with a minimum of 35 patients within each stratum.