



NEW CLINICAL TRIAL OPEN FOR INCLUSION



PROTOCOL TITLE

STEREOTACTIC BODY RADIATION THERAPY AFTER CHEMOTHERAPY FOR UNRESECTABLE PERIHILAR CHOLANGIOCARCINOMA: A MULTICENTER PHASE II TRIAL (THE STRONG 2 TRIAL)

ALIAS

STRONG 2

CTO NUMBER

CTO23020UZR

SPONSOR

Erasmus MC



KEY INCLUSION AND EXCLUSION CRITERIA

- Inclusion criteria: unresectable perihilar cholangiocarcinoma (according to Mayo Clinic criteria), single tumor, T1–4, N0–2, M0 disease, ECOG 0–1, Child-Pugh A (if cirrhosis), and eligibility for gemcitabine-based chemotherapy.
- For the SBRT part, patients must **in addition** have measurable disease per RECIST 1.1, have completed gemcitabine-based chemotherapy (\pm immunotherapy) without disease progression, meet predefined hematologic and liver function criteria, and be able to start SBRT within 12 weeks after completion of systemic treatment.
- Key exclusion criteria: Prior liver surgery, transplantation or liver radiotherapy, local tumor extension into stomach, duodenum, colon, pancreas or abdominal wall, ascites, extra-regional nodal disease or distant metastases, pregnancy, and—specific to the SBRT part—any local or distant disease progression during or after chemotherapy.



DESIGN

- Radiotherapy part: single-arm, multicenter phase II study enrolling 30 patients with unresectable perihilar cholangiocarcinoma who have completed gemcitabine-based chemotherapy (\pm immunotherapy) without progression, evaluating SBRT delivered in 15 fractions of 4-4,5 Gy as an add-on treatment, with local tumor control as the primary endpoint and toxicity, PFS, OS and quality of life as secondary endpoints.
- Translational part: An exploratory translational component includes peripheral blood sampling before and after chemotherapy to assess immunodynamic biomarkers and explore their predictive value for progression-free and overall survival.



PRINCIPAL INVESTIGATOR

Dr. Ines Joye

Ines.Joye@zas.be

STUDY COORDINATOR(S)

Abdelbari Baitar

Abdelbari.Baitar@zas.be

Kathleen Traets

Kathleen.Traets@zas.be