

International study on ex situ Liver Surgery Outcomes - ExSituLiver.org

Introduction: Ex situ liver surgery allows liver resection with vascular reconstruction in patients who have liver tumors at surgically critical locations. Only few studies with a low number of cases about ex situ liver surgery are currently available in the literature, most limited to short-term outcomes. The aim of this study is to identify the true world-wide morbidity, mortality, and long-term outcomes after ex situ liver surgery. The second aim is to identify modifiable predicting factors to improve the outcomes after ex situ liver surgery.

Eligibility: Any surgeon worldwide performing ex situ liver surgery is eligible to participate in this study. There are no minimum number of cases to be submitted or selection criteria for centers.

Time period and team members: Each participant may form a team of 3 members in total. Both prospective and retrospective patient enrolment is accepted. The end of the patient enrolment is set on 30 October 2023.

Inclusion criteria: Only ex situ liver surgery cases will be included allowing all indications (benign and malignant).

Exclusion criteria: Ante situm, or in situ liver surgery under hypothermic perfusion are excluded.

Outcomes: The primary endpoint of the analysis will be 90-day mortality. Secondary endpoints will be the 90-day postoperative complication rates, liver failure rates requiring cadaveric liver transplantation, as well as up to 5 year overall and disease free survival.

Data ownership: The headquarters at the University of Zaragoza, Spain will act as the custodian of the data. The Chief Investigators and Scientific Committee together will decide after the publication of the main report about requests regarding secondary analysis and will consider all such requests based on quality and the validity of the proposed project and decide by majority decision. All participants will be able to download their own submitted data in excel format without any need for permission from the study sponsor.

Authorship: All collaborators will become authors in all publications derived from this study. The order of authorship will be based on the total number of cases submitted in a descending manner. The first author will be the one that drafts the manuscript and the last author the corresponding, senior author.

Participation: Register your participation at ExSituLiver.org, obtain all necessary ethics approval documents, and submit your cases at ExSituLiver.org platform.