An international study to investigate rates of death and illness following liver surgery

Submission date	Recruitment status	Prospectively registered			
03/12/2018 No longer recruiting		☐ Protocol			
Registration date	Overall study status	Statistical analysis plan			
13/02/2019	Completed	[X] Results			
Last Edited	Condition category	Individual participant data			
06/03/2024	Surgery				

Plain English summary of protocol

Background and study aims

The safety of liver surgery has dramatically improved over the last 20 years, however complications and death rates differ among countries and hospitals. LiverGroup.org is a collaborative project of liver surgeons worldwide to study the complications and death rates of patients after liver surgery. LiverGroup.org is conducting a worldwide clinical audit that seeks to assess the complication and death rates of patients undergoing liver surgery. Clinical audit is a way to find out if healthcare is being provided in line with standards and lets care providers and patients know where there could be improvements. This type of audit is called a "snapshot" clinical audit as it will record data during a short period of time. The aim is to allow quality improvement to take place where it will be most helpful and will improve outcomes (i.e. complication and death rates) for patients.

Who can participate?

Adult patients (18 years or older) undergoing liver surgery

What does the study involve?

Liver surgeons will enter information in a password-protected and encrypted electronic database. The information will be anonymous data of patients undergoing liver surgery over a 3-month period worldwide.

What are the possible benefits and risks of participating?

There will be no direct health benefit for participants (including no reimbursement of gifts or money) but participation is very likely to help us improve the practice of liver surgery and hence future generations are likely to benefit from it. There are no risks of participating in the study, because there are no changes to treatment as a results of participation.

Where is the study run from?

University of Zaragoza (Spain) and University College London (UK)

When is the study starting and how long is it expected to run for? December 2015 to March 2020.

Who is funding the study?
University of Zaragoza (Spain) and University College London (UK)

Who is the main contact?
Dr Dimitri Raptis, dimitri.raptis@nhs.net

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT03768141

Protocol serial number

v.1.3

Study information

Scientific Title

International Snapshot Study on the Outcomes of Liver surgery - LiverGroup.org

Acronym

LiverGroup.org

Study objectives

The International Liver Surgery Outcomes Study – LiverGroup.org aims to measure the true worldwide practice of liver surgery and associated outcomes by recruiting multiple international centres, committing to consecutive patient registration per surgeon and undergo rigorous data validation. It is hoped that these data will provide a more appropriate guide to inform surgeons and patients to assess which level of complexity should be routinely offered for high tumour burden and anatomically difficult scenarios.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This project is considered as an audit and does not require ethics committee approval in the UK.

Study design

Observational snapshot study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Any indication for liver surgery

Interventions

The intervention includes any type of liver surgery. The patients's progress will be observed from the day of the operation until hospital discharge as well as up to 90 days postoperatively.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Death recorded up to 90 days postoperatively using the patients' medical records

Key secondary outcome(s))

- 1. Postoperative complications as measured by the Clavien-Dindo Classification, FABIB Liver-Specific Classification and the Comprehensive Complication Index\$ (CCI\$)
- 2. Liver failure as measured by the FABIB Liver-Specific Classification, the ISGLS criteria and the 50-50 criteria up to 90 days postoperatively
- 3. Length of hospital stay (defined as the duration of hospitalization from the day of the operation until the day of discharge from the hospital) recorded up to 90 days postoperatively using the patients' medical records
- 4. Rehospitalization (defined as any readmission to any hospital within 90 days from the operation) assessed using the patients' medical records up to 90 days postoperatively using the patients' medical records

Completion date

10/03/2020

Eligibility

Key inclusion criteria

1. All liver surgery indications (including benign and living donor resections, open, laparoscopic or robotic surgery, single wedge resections to extended liver resections, single- or two-stage

hepatectomies, procedures with liver volume enhancement such as PVE, PVL, ALPPS, resections involving cold perfusion (ex-situ and ante-situ) 2. Any co-morbidity Participant type(s) **Patient** Healthy volunteers allowed No Age group Adult Sex All Key exclusion criteria 1. Liver transplantation 2. Imaging-guided RFA, MWA, or other ablation techniques 3. Liver biopsies Date of first enrolment 01/01/2019 Date of final enrolment 31/12/2019 Locations Countries of recruitment United Kingdom England Afghanistan Åland Islands Albania Algeria American Samoa Andorra

Angola

Anguilla

Antarctica

Antigua and Barbuda
Argentina
Armenia
Aruba
Australia
Austria
Azerbaijan
Bahamas
Bahrain
Bangladesh
Barbados
Belarus
Belgium
Belize
Benin
Bermuda
Bhutan
Bolivia
Bonaire Saint Eustatius and Saba
Bosnia and Herzegovina
Botswana
Bouvet Island
Brazil
British Indian Ocean Territory
Brunei Darussalam
Bulgaria

Burkina Faso
Burundi
Cabo Verde
Cambodia
Cameroon
Canada
Cayman Islands
Central African Republic
Chad
Chile
China
Christmas Island
Cocos (Keeling) Islands
Colombia
Comoros
Congo
Congo, Democratic Republic
Cook Islands
Costa Rica
Croatia
Cuba
Curaçao
Cyprus
Czech Republic
Côte d'Ivoire
Denmark

Djibouti
Dominica
Dominican Republic
Ecuador
Egypt
El Salvador
Equatorial Guinea
Eritrea
Estonia
Eswatini
Ethiopia
Falkland Islands
Faroe Islands
Fiji
Fiji Finland
-
Finland
Finland France
Finland France French Guiana
Finland France French Guiana French Polynesia
Finland France French Guiana French Polynesia French Southern Territories
Finland France French Guiana French Polynesia French Southern Territories Gabon
Finland France French Guiana French Polynesia French Southern Territories Gabon Gambia
Finland France French Guiana French Polynesia French Southern Territories Gabon Gambia Georgia
Finland France French Guiana French Polynesia French Southern Territories Gabon Gambia Georgia Germany

Greenland
Grenada
Guadeloupe
Guam
Guatemala
Guernsey
Guinea
Guinea-Bissau
Guyana
Haiti
Heard Island and McDonald Islands
Holy See (Vatican City State)
Honduras
Hong Kong
Hungary
Iceland
India
Indonesia
Iran
Iraq
Ireland
Isle of Man
Israel
Italy
Jamaica
Japan

Jersey
Jordan
Kazakhstan
Kenya
Kiribati
Korea, North
Korea, South
Kosovo
Kuwait
Kyrgyzstan
Lao People's Democratic Republic
Latvia
Lebanon
Lesotho
Liberia
Libya
Liechtenstein
Lithuania
Luxembourg
Macao
Madagascar
Malawi
Malaysia
Maldives
Mali
Malta

Marshall Islands
Martinique
Mauritania
Mauritius
Mayotte
Mexico
Micronesia, Federated States of
Moldova
Monaco
Mongolia
Montenegro
Montserrat
Могоссо
Mozambique
Myanmar
Namibia
Nauru
Nepal
Netherlands
New Caledonia
New Zealand
Nicaragua
Niger
Nigeria
Niue
Norfolk Island

North Macedonia
Northern Mariana Islands
Norway
Oman
Pakistan
Palau
Palestine, State of
Panama
Papua New Guinea
Paraguay
Peru
Philippines
Pitcairn
Poland
Portugal
Puerto Rico
Qatar
Romania
Russian Federation
Rwanda
Réunion
Saint Barthélemy
Saint Helena, Ascension and Tristan da Cunha
Saint Kitts and Nevis
Saint Lucia
Saint Martin (French part)

Saint Pierre and Miquelon
Saint Vincent and the Grenadines
Samoa
San Marino
Sao Tome and Principe
Saudi Arabia
Senegal
Serbia
Seychelles
Sierra Leone
Singapore
Sint Maarten (Dutch part)
Slovakia
Slovenia
Solomon Islands
Somalia
South Africa
South Georgia and the South Sandwich Islands
South Sudan
Spain
Sri Lanka
Sudan
Suriname
Svalbard and Jan Mayen
Sweden
Switzerland



Zambia Zimbabwe Study participating centre Royal Free London NHS Foundation Trust, UCL Partners Pond Street London **United Kingdom** NW3 2QG Study participating centre University Hospital Miguel Servet Department of Surgery University Hospital Miguel Servet University of Zaragoza Calle Gonzalo Calamita Zaragoza Spain 50009 Sponsor information Organisation Royal Free London NHS Foundation Trust **ROR** https://ror.org/04rtdp853

Department of Surgery, University Hospital Miguel Servet, University of Zaragoza, Spain

Virgin Islands, U.S.

Wallis and Futuna

Western Sahara

Organisation

Yemen

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Royal Free Hospital

Alternative Name(s)

The Royal Free

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Funder Name

Universidad de Zaragoza

Alternative Name(s)

Saragossa University, School of Zaragoza, University of Zaragoza, Unizar, Universidad Zaragoza, UZ

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Spain

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be available upon request from the Management Committee of LiverGroup.org

The study Primary Investigators will act as the custodians of the data. The data however belong to all collaborators. The steering and management committees 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.

The members of LiverGroup.org that have already actively participated in the study and have contributed with cases may contact the Management Committee of LiverGroup.org using the online form (available at: https://livergroup.org/?q=contact) or by email (office@livergroup.org) with their request of the raw data for additional analyses.

All data provided in the form of an Excel database will by fully anonymized without any patient identifiers.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2023	06/03/2024	Yes	No
Participant information sheet	version v4		13/02/2019	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes