

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

<b>Submission date</b> 03/12/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/02/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/03/2024	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## 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  
Finland  
France  
French Guiana  
French Polynesia  
French Southern Territories  
Gabon  
Gambia  
Georgia  
Germany  
Ghana  
Gibraltar  
Greece

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

Morocco

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

Syria  
Taiwan  
Tajikistan  
Tanzania  
Thailand  
Timor-Leste  
Togo  
Tokelau  
Tonga  
Trinidad and Tobago  
Tunisia  
Turkmenistan  
Turks and Caicos Islands  
Tuvalu  
Türkiye  
Uganda  
Ukraine  
United Arab Emirates  
United States Minor Outlying Islands  
United States of America  
Uruguay  
Uzbekistan  
Vanuatu  
Venezuela  
Viet Nam  
Virgin Islands, British

Virgin Islands, U.S.

Wallis and Futuna

Western Sahara

Yemen

Zambia

Zimbabwe

**Study participating centre**

**Royal Free London NHS Foundation Trust, UCL Partners**

Pond Street

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**Study participating centre**

**University Hospital Miguel Servet**

Department of Surgery

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50009

## **Sponsor information**

**Organisation**

Royal Free London NHS Foundation Trust

**ROR**

<https://ror.org/04rtdp853>

**Organisation**

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

# 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, L'université de Saragosse, 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](mailto:office@livergroup.org)) with their request of the raw data for additional analyses.

All data provided in the form of an Excel database will be 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?
<a href="#">Results article</a>		01/12/2023	06/03/2024	Yes	No
<a href="#">Participant information sheet</a>	version v4		13/02/2019	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes