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

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

Plain English Summary
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

Study website
https://livergroup.org/

Contact information

Type(s)
Scientific

Contact name
Dr Dimitri Raptis

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03768141

Secondary identifying numbers
v.1.3

Study information

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

Acronym
LiverGroup.org

Study hypothesis

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

Secondary study design
Epidemiological study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

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

Secondary outcome measures
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

Overall study start date
12/12/2015

Overall study end date
10/03/2020

Eligibility

Participant 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

Age group
Adult

Sex
Both

Target number of participants
2000

Participant exclusion criteria
1. Liver transplantation
2. Imaging-guided RFA, MWA, or other ablation techniques
3. Liver biopsies

Recruitment start date
01/01/2019

Recruitment end date
31/12/2019

Locations

Countries of recruitment
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

Cambodia

Cameroon

Canada

Cabo Verde

Cayman Islands

Central African Republic

Chad

Chile

China

Christmas Island

Cocos (Keeling) Islands

Colombia

Comoros

Congo

Congo, Democratic Republic

Cook Islands

Costa Rica

Côte d'Ivoire

Croatia

Cuba

Curaçao

Cyprus

Czech Republic

Denmark

Djibouti

Dominica

Dominican Republic

Ecuador

Egypt

El Salvador

England

Equatorial Guinea

Eritrea

Estonia

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

North Macedonia

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

Northern Mariana Islands

Norway

Oman

Pakistan

Palau

Palestine, State of

Panama

Papua New Guinea

Paraguay

Peru

Philippines

Pitcairn

Poland

Portugal

Puerto Rico

Qatar

Réunion

Romania

Russian Federation

Rwanda

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

Eswatini

Sweden

Switzerland

Syria

Taiwan

Tajikistan

Tanzania

Thailand

Timor-Leste

Togo

Tokelau

Tonga

Trinidad and Tobago

Tunisia

Türkiye

Turkmenistan

Turks and Caicos Islands

Tuvalu

Uganda

Ukraine

United Arab Emirates

United Kingdom

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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United Kingdom
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Study participating centre
University Hospital Miguel Servet
Department of Surgery
University Hospital Miguel Servet
University of Zaragoza
Calle Gonzalo Calamita
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Sponsor information

Organisation
Royal Free London NHS Foundation Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
https://www.royalfree.nhs.uk

ROR
https://ror.org/04rtdp853

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

Sponsor details
Calle Gonzalo Calamita
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almaley@telefonica.net

Sponsor type
Hospital/treatment centre

Website
http://sectorzaragozados.salud.aragon.es

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)
University of Zaragoza, Saragossa University, Universidad Zaragoza, UZ

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Spain

Results and Publications

Publication and dissemination plan
LiverGroup.org is a collaboration of all surgeons contributing data as equal partners. Each surgeon contributing data has access to analysis files of the entire database at any time point and the right to propose analyses and publish data as long as every surgeon contributing data are included as a group author in every publication and have an opportunity to review the data prior to submission. Each collaborator has access to their own data in a form of an Excel export file without requiring permission or approval by the LiverGroup.org management committee.

One single analysis without hierarchical authorship (no first author, no last author) is planned at the end of the study (a “pure” group author publication) to reflect the collaborative effort. Any member of the group is encouraged to step forward with secondary analyses on specific

questions and will have full access to the data. There will be no need for approval of publication of data from The LiverGroup.org collaboration, but all group authors have the right to review the manuscripts and have to be given at least 1 week to be able to review the manuscripts.

Intention to publish date

01/06/2020

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?
Participant information sheet	version v4		13/02/2019	No	Yes
Results article		01/12/2023	06/03/2024	Yes	No