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International living donor liver transplant registry – LDLTregistry.org

Submission date 06/02/2023	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/05/2023	**Overall study status** Ongoing	
Last Edited 31/05/2023	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Living donor liver transplantation (LDLT) was introduced in the early 1990s to overcome an increasing shortage of available deceased donor organs for transplantation. LDLT remains the main source of grafts for liver transplantation in Asian countries. However, reports on donor illness and even death have hampered the uptake of the procedure in Western countries. Outcome data are available from developed countries, but outcomes in developing countries remain unknown. There is a need to collect data from all parts of the world to create a single prospective registry and allow meaningful comparisons, as well as standardization of the procedure, across the globe.

Who can participate?
Any center worldwide involved in LDLT is eligible to participate in this registry. There are no minimum number of cases to be submitted or selection criteria for centers. Cases must be prospectively registered. Both donors and recipients will be included in the registry, including adult and pediatric, two-stage LDLT, as well as dual grafts. Domino grafts will be excluded.

What does the study involve?
The researchers have developed a worldwide registry that seeks to assess the complication rates of donors and recipients undergoing living donor liver transplantation. Audits and registries are a way to find out if healthcare is being provided in line with standards and allow care providers and patients to envision potential improvements. Healthcare providers across the world submit anonymized case details of patients undergoing living donor liver transplantation. This acts as a central database until the end of the trial period when primary analysis will take place.

What are the possible benefits and risks of participating?
There will be no direct health benefit for the participants but their participation is very likely to help to improve the practice of living donor liver transplantation and hence future generations are likely to benefit from it. There are no risks of participating.

Where is the study run from?
Klinik Hirslanden (Switzerland)

When is the study starting and how long is it expected to run for?
April 2023 to September 2033

Who is funding the study?
1. Rela Institute (India)
2. International Liver Transplant Society (ILTS)
3. International Living Donor Liver Transplantation (iLDLT) Group

Who is the main contact?
Dr Dimitri Raptis, dimitri.raptis@gmail.com

Study website
https://ldltregistry.org

Contact information

Type(s)
Principal Investigator

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AO_2023-00013

Study information

Scientific Title
International living donor liver transplant registry

Acronym
LDLTregistry.org

Study objectives
Living donor liver transplantation (LDLT) was introduced in the early 1990s to overcome an increasing shortage of available deceased donor organs for transplantation. LDLT remains the main source of grafts for liver transplantation in Asian countries, however, reports on donor morbidity and even mortality have hampered the uptake of the procedure in Western countries. Outcome data are available from developed countries, but outcomes in developing countries remain unknown. There is a need to collect data from all parts of the world, to create a single prospective registry and allow meaningful comparisons, as well as standardization of the procedure, across the globe.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/04/2023, Kantonale Ethikkomission Zürich (Klinik Hirslanden Zürich vivévis AG PD Dr. med. univ. Christian Oberkofler, Kappelistrasse 7 8002, Zürich, Switzerland; +41 (0)43 259 79 70; admin.kek@kek.zh.ch), ref: AO_2023-00013

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital, Medical and other records

Study type(s)
Treatment

Participant information sheet
https://ldltregistry.org/patient_info_consent

Health condition(s) or problem(s) studied
Living donor liver transplantation

Interventions
A global prospective registry of perioperative morbidity and mortality post-LDLT will be established to collect data for donors and recipients. All clinicians involved in LDLT are eligible to submit data to the registry. Data will be collected until hospital discharge and up to 90 days postoperatively. The primary endpoint of the analysis is 90-day morbidity and mortality for both recipients and donors. Secondary endpoints include the identification of modifiable predictors of outcome. Additional outcome data will be captured and analysed after 12 months of follow-up.

Intervention Type
Other

Primary outcome measure
Morbidity and mortality for both the donor and recipient until hospital discharge and up to 90 days postoperatively, collected from patients' medical records, operation reports and information from electronic patient records

Secondary outcome measures
Identification of modifiable predictors of outcome at 90 days post-operation, collected from patients' medical records, operation reports and information from electronic patient records. Additional outcome data will be captured at 12 months follow up

Overall study start date
01/04/2023

Completion date
01/09/2033

Eligibility

Key inclusion criteria
1. Cases must be prospectively registered
2. Both donors and recipients will be included in the registry, including adult and pediatric, two-stage LDLT (e.g. Auxiliary, RAPID, APOLT, ASPIRE, RAVAS), as well as dual grafts

RAPID = Resection And Partial lIver segment 2–3 transplantation with Delayed total hepatectomy
APOLT = Auxiliary Partial Orthotopic Living Donor Liver Transplantation

ASPIRE = Auxiliary two-Staged PartIal REsection liver transplantation
RAVAS = Heterotopic transplantation of segments 2 and 3 using the splenic vein and artery after splenectomy and with delayed total hepatectomy

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
2000

Key exclusion criteria
Domino grafts

Date of first enrolment
01/09/2023

Date of final enrolment
01/09/2027

Locations

Countries of recruitment
Afghanistan

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

England

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 Ireland

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

Scotland

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 Kingdom

United States Minor Outlying Islands

United States of America

Uruguay

Uzbekistan

Vanuatu

Venezuela

Viet Nam

Virgin Islands, British

Virgin Islands, U.S.

Wales

Wallis and Futuna

Western Sahara

Yemen

Zambia

Zimbabwe

Åland Islands

Study participating centre
Hirslanden Zürich
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Sponsor information

Organisation
Klinik Hirslanden

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/014c2qb55

Funder(s)

Funder type
Research organisation

Funder Name
Rela Institute

Funder Name
International Liver Transplant Society (ILTS)

Funder Name
International Living Donor Liver Transplantation (iLDLT) Group

Results and Publications

Publication and dissemination plan
All LDLTregistry.org members, with submitted verified cases to the registry, will be PubMed cited as group authors in the main publications. Spin-off studies may include formal named authorship but must include the “LDLTregistry.org Collaborative” with group authorship for all participants.

Intention to publish date
01/09/2024

Individual participant data (IPD) sharing plan
LDLTregistry.org will act as the custodian of the data. All participants will be able to access their own submitted data without the need for permission from the LDLTregistry.org Committees. The Chief Investigators, Scientific and Management committees together will decide about data sharing requests and will consider all such requests based on the quality and validity of the proposed project.

The datasets generated during and/or analysed during the current study are/will be available upon request from Dimitri Raptis (dimitri.raptis@gmail.com)/ All data-sharing requests are to be considered on a case-by-case basis. Participating centers have the responsibility to request ethics approval for their respective recruiting centers and obtain written informed consent as per the legislation of the countries of the recruiting and participating centers. All data is anonymised such that individual patient identifying information is anonymised and details regarding individual operating clinicians are also anonymised.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	version 1	30/05/2023	No	Yes
Protocol file	version 7	31/05/2023	No	No