ISRCTN95140761 https://doi.org/10.1186/ISRCTN95140761

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

Submission date
25/11/2020

Recruitment status
No longer recruiting

Registration date
03/12/2020

Overall study status
Completed

Last Edited
20/05/2024

Condition category
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Although death after pancreatic surgery has decreased significantly in specialised high-volume centres, the number of people with pancreatic diseases still remains high. Complexity and extent of pancreatic operations, patient selection, centre and surgeon experience all influence the outcomes following an operation. Furthermore, patients present at an older age and with other diseases which increase the risk of postoperative complications. The aim of PancreasGroup.org is to identify the true world-wide morbidity and mortality of pancreatic operations. The second aim is to identify modifiable predicting factors to improve the outcomes after pancreatic surgery.

Who can participate?
Adult patients (18 years or older) undergoing pancreatic surgery

What does the study involve?
Pancreatic surgeons will enter information in a password-protected and encrypted electronic database. The information will be anonymous data of patients undergoing pancreatic 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 pancreatic 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?
1. Royal Free Hospital, London (UK)
2. Massachusetts General Hospital, Boston (USA)

When is the study starting and how long is it expected to run for?
September 2019 to March 2022

Who is funding the study?
1. Royal Free Hospital, London (UK)
2. Massachusetts General Hospital, Boston (USA)

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

Study website
https://pancreasgroup.org/

Contact information

Type(s)
Scientific

Contact name
Dr Dimitri Aristotle Raptis

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RFH287_20-21

Study information

Scientific Title
International Pancreatic Surgery Outcomes Study - PancreasGroup.org

Acronym

PancreasGroup.org

Study objectives
The aim of PancreasGroup.org is to identify the true world-wide morbidity and mortality of pancreatic operations. The second aim is to identify modifiable risk factors to improve the outcomes after pancreatic surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethics approval required. Registered and approved as an audit by the Royal Free Hospital Quality Governance Department with the ID number RFH287_20-21

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
https://pancreasgroup.org/sites/default/files
/Patient_Information_and_Consent_form_PancreasGroup.org_v1.docx

Health condition(s) or problem(s) studied
Patients with pancreatic disease requiring surgery

Interventions
Participants, agreeing to be part of this study, will be observed from the date of surgery until hospital discharge as well as 90 days after their operation. Fully anonymised data will be collected including the participant, their disease, operation characteristics as well as outcomes, such as events including death and illness.

Intervention Type
Procedure/Surgery

Primary outcome measure
Mortality rate 90 days postoperatively measured using patient records

Secondary outcome measures

Morbidity as defined by the Clavien-Dindo Classification and measured by the Comprehensive Complications Index ® (CCI®) at 90 days postoperatively measured using patient records

Overall study start date
21/09/2019

Completion date
31/03/2022

Eligibility

Key inclusion criteria
1. Adults 18 years of age or older
2. All indications (including benign and malignant)
3. Open, laparoscopic or robotic
4. Elective or emergency
5. Partial or total pancreatectomies
6. Pancreatic tumour enucleations
7. Procedures with concomitant vascular or other organ resections
8. Pancreatic duct drainage procedures (e.g. Frey, Puestow, or Beger)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
We anticipate over 3,500 cases submitted worldwide. This will allow meaningful comparisons regarding mortality rates.

Total final enrolment
4223

Key exclusion criteria
1. Pancreas or islet cell transplantation
2. Transcutaneous or transgastric imaging-guided ablation (e.g. RFA) or electroporation (e.g. NanoKnife)
3. Endoscopic (e.g. ERCP, stent or lithotripsy) procedures
4. Endoscopic transgastric and surgical necrosectomies

Date of first enrolment
01/01/2021

Date of final enrolment
31/12/2021

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 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 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

Åland Islands

Study participating centre

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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/04rtdp853

Funder(s)

Funder type
Charity

Funder Name
Royal Free Charity - Fiorina Fund

Results and Publications

Publication and dissemination plan
PancreasGroup.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 PancreasGroup.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 PancreasGroup.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
01/07/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from Dr Dimitri Raptis, dimitri.raptis@nhs.net on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/01/2024	20/05/2024	Yes	No