

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/12/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/04/2026	Condition category Surgery	<input type="checkbox"/> 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

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Mortality rate 90 days postoperatively measured using patient records

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

110 years

Sex

All

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

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

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Sponsor information

Organisation

Royal Free London NHS Foundation Trust

ROR

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

Funder(s)

Funder type

Charity

Funder Name

Royal Free Charity - Fiorina Fund

Results and Publications

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
Results article	Short-term outcomes in pancreatic surgery with vascular resection	26/08/2025	21/04/2026	Yes	No
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