

Resolution of organ injury in acute pancreatitis

Submission date 08/11/2017	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 13/11/2017	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 15/04/2024	Condition category Digestive System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Acute pancreatitis is inflammation of the pancreas, usually triggered by gallstones or excess alcohol use. At the moment, the medium to long-term effects of pancreatitis on individual organ systems are not known (e.g. the lungs and kidneys). It is known that people who have a severe attack of pancreatitis have a shorter overall life expectancy than those who have a mild attack. Because the cells in the body that produce insulin are located in the pancreas, when the pancreas gets damaged by inflammation, some people lose the function of their insulin-producing cells and can become diabetic. The aim of this study is to assess long-term organ function after an episode of acute pancreatitis.

Who can participate?

Patients aged over 16 with acute pancreatitis treated at Royal Infirmary Edinburgh

What does the study involve?

Participants have their overall health and specific organ function assessed at the time of their acute episode, 3 months afterwards, and again 2 years after that. Additional heart and lung tests, blood tests of the immune system, and imaging to assess structure and function of key organ systems are also conducted in some of the participants.

What are the possible benefits and risks of participating?

This study will help with understanding what the long-term negative effects of an episode of pancreatitis are. Although no new treatments are tested in this study, the results may lead to the development of better ways of caring for people who have had an episode of acute pancreatitis. There are no direct benefits to individual participants as individual study data is not shared with participants, and there is no treatment or alteration of standard care for participants. With regard to risks, these are minimal, and are associated with blood sampling.

Where is the study run from?

1. Royal Infirmary Edinburgh (UK)
2. Wellcome Trust Clinical Research Facility (UK)

When is the study starting and how long is it expected to run for?

September 2015 to March 2022

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof Damian Mole

Contact information

Type(s)
Scientific

Contact name
Prof Damian Mole

Contact details
MRC Centre for Inflammation Research (W2.16)
Queen's Medical Research Institute
The University of Edinburgh
47 Little France Crescent
Edinburgh
United Kingdom
EH16 4JT

Additional identifiers

ClinicalTrials.gov (NCT)
NCT03342716

Protocol serial number
v8 01 Dec 2017

Study information

Scientific Title
Resolution of Organ Injury in Acute Pancreatitis (RESORP): an observational cohort study with a nested cohort

Acronym
RESORP

Study objectives
To define long-term organ hypofunction after an episode of acute pancreatitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland Research Ethics Committee 01, 15/04/2016, REC ref: 16/SS/0065

Primary study design

Observational

Study design

Observational cohort study with a nested cohort

Study type(s)

Other

Health condition(s) or problem(s) studied

Acute pancreatitis

Interventions

The cohort assessment will comprise of 3 study visits. In-depth assessments of a participant's health at presentation, at 3 months and at 27 months after the first episode of acute pancreatitis will be obtained. Additional cardiorespiratory evaluation tests, specialised blood tests of the immune system, tests for precision medicine, and imaging to assess structure and function of key organ systems will be conducted in a nested cohort of participants.

For the whole cohort (estimated 500 individuals, each tested three times (at recruitment, 3 months and 27 months after AP):

1. Full peripheral venous blood profiling, including cardiac biomarkers, standard biochemistry profiling, and samples retained for miRNA profiling, cytokines, telomere length, metabolomic profiling, proteomic profiling, transcriptomic profiling, genomic profiling, leukocyte subset analysis by flow cytometry
2. Biochemical markers of organ function in urine and samples retained
3. Pancreatic exocrine function test in stool (faecal elastase) and samples retained
4. Nutritional assessment
5. Oral glucose tolerance test at 3 and 27-month follow-up visit (measure random glucose level only in insulin dependent diabetics)
6. 12-lead electrocardiogram (ECG), blood pressure
7. Peripheral SpO2
8. Sway balance app, non-invasive muscle function tests
9. Self-administered Patient Questionnaire:
 - 9.1. Gastrointestinal Quality of Life Index (GIQLI)
 - 9.2. SF-12 Quality of Life
 - 9.3. Montreal Cognitive Assessment

Intervention Type

Other

Primary outcome(s)

The incidence of new onset type 3c diabetes mellitus in patients with AP measured at 27 months, compared to the age matched population of Scotland

Key secondary outcome(s)

Full peripheral venous blood profiling, including cardiac biomarkers, standard biochemistry profiling, and samples retained for miRNA profiling, cytokines, telomere length, metabolomic profiling, proteomic profiling, transcriptomic profiling, genomic profiling, leukocyte subset analysis by flow cytometry, at recruitment, 3 months and 27 months after AP

Completion date

31/03/2022

Eligibility

Key inclusion criteria

1. All patients treated at Royal Infirmary Edinburgh with a clinical or radiological diagnosis of acute pancreatitis will be recruited where possible
2. For the potential clinical diagnosis of acute pancreatitis an appropriate clinical history based on compatible clinical features, will be required (i.e. abdominal pain, nausea and/or vomiting), supported by the finding of elevated serum amylase greater than 3x the upper limit of the reference range for the laboratory (currently 300 U/L)
3. For the radiological diagnosis, if applicable, computerised tomography (CT) and/or ultrasound scan (USS) evidence of acute pancreatitis will be accepted
4. With the exception of prisoners, all adult patients with capacity to give informed consent will be considered

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 Years

Sex

All

Total final enrolment

229

Key exclusion criteria

Current exclusion criteria as of 09/04/2024:

1. Patients under the age of 16 years will be excluded from the present study
2. Prisoners will be excluded from the present study
3. Patients lacking the capacity to consent will be excluded but can be included if they regain capacity during the hospital admission

The additional two exclusions below apply only to those patients being considered for the nested cohort study:

4. Patients not able to undergo MRI scanning for technical reasons will be excluded (e.g. those with cochlear implants, implanted pacemaker)
5. Patients with a known allergy to salbutamol

Previous Participant exclusion criteria (as of 18/12/2017):

1. Patients under the age of 16 years will be excluded from the present study
2. Prisoners will be excluded from the present study
3. Patients lacking the capacity to consent will be excluded but can be included if they regain capacity

The additional two exclusions below apply only to those patients being considered for the nested cohort study:

4. Patients not able to undergo MRI scanning for technical reasons will be excluded (e.g. those with cochlear implants, implanted pacemaker)
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Date of first enrolment

27/11/2017

Date of final enrolment

12/03/2020

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Royal Infirmary Edinburgh

51 Little France Crescent

Edinburgh

United Kingdom

EH16 4SA

Study participating centre

Wellcome Trust Clinical Research Facility
Royal Infirmary Edinburgh
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA

Sponsor information

Organisation

The University of Edinburgh

Organisation

NHS Lothian

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Study website	07/12/2020	10/03/2022	Yes	No
HRA research summary			28/06/2023	No	No
Study website		11/11/2025	11/11/2025	No	Yes