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Resolution of organ injury in acute pancreatitis

Submission date	Recruitment status	[X] Prospectively registered
08/11/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/11/2017	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/04/2024	Digestive System	[_] 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

Study website
https://www.ed.ac.uk/usher/edinburgh-clinical-trials/our-studies/ukcrc-studies/resorp

Contact information

Type(s)
Scientific

Contact name
Prof Damian Mole

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

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT03342716

Secondary identifying numbers
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

Study design
Observational cohort study with a nested cohort

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/09/2015

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

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
500

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
Scotland

United Kingdom

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

Sponsor details
The Queen's Medical Research Institute
47 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4TJ

Sponsor type
University/education

Website
http://www.accord.ed.ac.uk

Organisation
NHS Lothian

Sponsor details
The Queen’s Medical Research Institute
47 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4TJ

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The intention is to publish the protocol and supporting material in the scientific literature and this will be made available online in due course. Planned publication of the results in a high-impact peer-reviewed journal.

Intention to publish date
31/07/2026

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		07/12/2020	10/03/2022	Yes	No
HRA research summary			28/06/2023	No	No