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What are the first measurable signs of the early phase of chronic pancreatitis?

Submission date 03/12/2018	**Recruitment status** Suspended	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/02/2019	**Overall study status** Ongoing	
Last Edited 11/01/2024	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Chronic pancreatitis (CP) is a severe disease which might be prevented by changing diet, smoking, alcohol consumption habits, and physical activity, however it is not known what to suggest to patients to decrease the risk of disease development. This study aims to find the first signs of the disease, when the progression could be slowed down and the prevention of recurrent acute pancreatitis (RAP) and CP could be started at the optimal time. The aim is to find the risk factors which worsen the progress of acute pancreatitis (AP) to RAP and CP. With this information, we could save lives, enhance the quality of life of patients, reduce the costs of health care, and new therapeutic targets could also be identified.

Who can participate?
Patients with acute pancreatitis enrolled in the GOULASH study

What does the study involve?
Participants are followed up 1, 2, 3, 4, 5 and 6 years after the episode of AP. Data about eating habits, stress and physical activity will be collected by questionnaires. Laboratory tests are carried out on blood samples and genetic tests are performed for the genes already known to be associated with CP. The researchers also test for diabetes and ineffective pancreas enzyme production. Pancreas imaging is also performed every year. Blood and faeces samples are stored in the biobank for later laboratory tests.

What are the possible benefits and risks of participating?
Participants might benefit from regular and thorough monitoring for the earliest signs of CP development. The only potential disadvantage in participating is that filling in the questionnaires is time-consuming and must be filled in with the help of a trained healthcare worker, which means it can’t be done prior to the follow-up visit.

Where is the study run from?
It is a multicentre trial, open for centres who take part in the GOULASH study, designed with help of the Centre for Translational Medicine at the University of Pécs, the leading centre of the study.

When is the study starting and how long is it expected to run for?
December 2017 to February 2030

Who is funding the study?
The University of Pécs using grants from the Hungarian government

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Observational longitudinal multicentre investigation of acute pancreatitis. (GOULASH PLUS): Follow-up of the GOULASH study

Acronym
GOULASH PLUS

Study objectives
Current hypothesis as of 08/04/2019:
Acute pancreatitis (AP) is an inflammatory condition, which can lead to late consequences. In 20% of patients recurrent AP (RAP) develops and in 7-12% chronic pancreatitis (CP) occurs. Chronic pancreatitis (CP) usually diagnosed at the end-stage, when fibrosis and exocrine and/or endocrine insufficiency are present. There is no gold standard therapy yet. In order to detect the first signs, risk factors and measurable parameters of early CP we plan to follow the late complications of acute and recurrent pancreatitis. By the early recognition of CP or the risks of CP the outcome of the disease can be improved, life expectancy can be increased, therefore the quality of life can improve and costs can be decreased.

The aim of the GOULASH-PLUS study is to understand the influencing factors and to determine which parameters should be measured to detect the early phase of CP.

Previous hypothesis:
Acute pancreatitis (AP) is an inflammatory condition, which can lead to late consequences. In 20% of patients recurrent AP (RAP) develops and in 5% chronic pancreatitis (CP) occurs. Chronic pancreatitis (CP) usually diagnosed at the end-stage, when fibrosis and exocrine and/or endocrine insufficiency are present. There is no gold standard therapy yet. In order to detect the first signs, risk factors and measurable parameters of early CP we plan to follow the late complications of acute and recurrent pancreatitis. By the early recognition of CP or the risks of CP the outcome of the disease can be improved, life expectancy can be increased, therefore the quality of life can improve and costs can be decreased.

The aim of the GOULASH-PLUS study is to understand the influencing factors and to determine which parameters should be measured to detect the early phase of CP.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/02/2018, Secretary of Medical Research Council Scientific and Research Ethics Committee (P.O.B 314, Budapest, H-1903, Hungary; (+36 1) 795 1192; attilane.gombos@bm.gov.hu), ref: 5753-2/2018/EKU

Study design
Observational prospective follow-up study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Acute pancreatitis

Interventions
Current intervention as of 08/04/2019:
This trial is designed as an observational study, no intervention is performed.
Anamnestic data will be collected by the following questionnaires at 1, 2, 3, 4, 5 and 6 years after

the episode of acute pancreatitis:
i) Diet History Questionnaire
ii) SF-36
iii) physical activity questionnaire
iv) stress questionnaire
Genetic tests will be performed for the genes already known to be associated with chronic pancreatitis.
The exocrine and endocrine pancreatic, liver and kidney functions will be determined by several laboratory tests and stool sample analyses at 1, 2, 3, 4, 5 and 6 years, and imaging (abdominal ultrasound in years 1, 3 and 5 and endoscopic ultrasound in years 2, 4 and 6).
Cost-effectiveness will be analyzed to examine the relationship between events of interest and health-related quality of life or to explore differences of the subgroup .
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Participants will be followed up at 1, 2, 3, 4 and 5 years after the episode of acute pancreatitis.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measures as of 08/04/2019:
1. Incidence of CP assessed once yearly for 6 years using abdominal ultrasound in years 1, 3 and 5 and endoscopic ultrasound in years 2, 4 and 6
2. Incidence of recurrent AP based on the IAP/APA guideline's 2 out of 3 rule. Patients will be followed up at least once a year for 6 years and will be asked to bring all medical records for review and discussion.
3. Incidence of exocrine pancreatic insufficiency assessed using the presence of steatorrhoea and the fecal elastase test assesed once yearly for 6 years
4. Incidence of endocrine pancreatic insufficiency (based on oral glucose tolerance test [OGTT] and fasting plasma glucose [FPG] test) once yearly for 6 years if the patient has not already been diagnosed with diabetes mellitus and the fasting plasma glucose level is ≤7 mmol/l

Previous primary outcome measures:
1. Incidence of CP assessed once yearly for 5 years using abdominal ultrasound in years 1, 3 and 4 and endoscopic ultrasound in years 2 and 5
2. Incidence of recurrent AP based on the IAP/APA guideline's 2 out of 3 rule. Patients will be

followed up at least once a year for 5 years and will be asked to bring all medical records for review and discussion.
3. Incidence of exocrine pancreatic insufficiency assessed using the presence of steatorrhoea and the fecal elastase test assesed once yearly for 5 years
4. Incidence of endocrine pancreatic insufficiency (based on oral glucose tolerance test [OGTT] and fasting plasma glucose [FPG] test) once yearly for 5 years if the patient has not already been diagnosed with diabetes mellitus and the fasting plasma glucose level is ≤7 mmol/l

Key secondary outcome(s))
Current secondary outcome measures as of 08/04/2019:
1. Need for radiological/surgical interventions assessed by reviewing patient medical records in every follow-up visit during the 6-year follow-up period.
2. Dietary intake assessed using Diet History Questionnaire (Version 2.0. National Institutes of Health) on follow-up visits once a year for 6 years
3. Quality of life assessed using RAND 36-Item Health Survey Version 1.0 SF-36 once a year for 6 years
4. Stress assessed using the 10-item Perceived Stress Scale once a year for 6 years
5. Physical activity assessed using International Physical Activity Questionnaire (IPAQ; long, usual week version) once a year for 6 years
6. Pain assessed by RAND 36-Item Health Survey Version 1.0 SF-36 once a year for 6 years
7. Development of pancreas tumor and cystic lesions assessed by reviewing patient medical records once a year for 6 years
8. Laboratory parameters to assess organ function – inflammatory cytokines, pancreatic peptides etc once a year for 6 years

Previous secondary outcome measures:
1. Need for radiological/surgical interventions assessed by reviewing patient medical records in every follow-up visit during the 5-year follow-up period.
2. Dietary intake assessed using Diet History Questionnaire (Version 2.0. National Institutes of Health) on follow-up visits once a year for 5 years
3. Quality of life assessed using RAND 36-Item Health Survey Version 1.0 SF-36 once a year for 5 years
4. Stress assessed using the 10-item Perceived Stress Scale once a year for 5 years
5. Physical activity assessed using International Physical Activity Questionnaire (IPAQ; long, usual week version) once a year for 5 years
6. Pain assessed by RAND 36-Item Health Survey Version 1.0 SF-36 once a year for 5 years
7. Development of pancreas tumor and cystic lesions assessed by reviewing patient medical records once a year for 5 years
8. Laboratory parameters to assess organ function – inflammatory cytokines, pancreatic peptides etc once a year for 5 years

Completion date
28/02/2030

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Diagnosed with AP on the basis of the '2 out of 3' rule of the IAP/APA guideline: (a) upper abdominal pain; (b) serum amylase or lipase >3x upper limit of normal range; (c) characteristic findings on pancreatic imaging; however those patients without abdominal pain will be excluded

because the onset of acute pancreatitis cannot be assessed
3. Participated in GOULASH study and signed the informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
31/01/2019

Date of final enrolment
28/01/2025

Locations

Countries of recruitment
Hungary

Study participating centre
University of Pécs Medical School Institute for Translational Medicine
Szigeti str 12
Pécs
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H-7624

Study participating centre
University of Debrecen 2nd Department of Internal Medicine, Division of Gastroenterology
98 Nagyerdei boulevard
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Study participating centre
Centre of Székesfehérvár Szent György University Teaching Hospital of Fejér County
3 Seregélyesi Street
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Study participating centre
Institute of Pancreatic Diseases, Semmelweis University
Tömő Street 25-29.
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Sponsor information

Organisation
University of Pécs, Medical School

ROR
https://ror.org/037b5pv06

Funder(s)

Funder type
University/education

Funder Name
University of Pécs Medical School

Funder Name
Momentum Grant of the Hungarian Academy of Sciences (LP2014-10/2014)

Funder Name
Highly Cited Publication Grant (KH 125678) of the National Research Development

Funder Name
Innovation Office (GINOP 2.3.2-15-2016-00048 Stay Alive)

Funder Name
Innovation Office (EFOP 3.6.2-16-2017-00006 Live Longer)

Funder Name
Translational Medicine Foundation

Results and Publications

Individual participant data (IPD) sharing plan
All parameters of the dataset will be available upon request from the principal investigator (Prof Péter Hegyi, University of Pécs Medical School Institute for Translational Medicine) after the results have been published.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/09/2019	21/08/2020	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes