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How can health-affecting individual lifestyle factors affect the risk of developing acute pancreatitis?

Submission date 15/10/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 22/01/2019	**Overall study status** Ongoing	
Last Edited 05/01/2024	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Acute pancreatitis (AP) is a sudden inflammation of the pancreas (an organ near the stomach that produces substances that aid digestion). AP is painful and can be life-threatening. It needs to be treated in hospital. This study aims to understand the lifestyle factors that increase or reduce the chance of developing AP. This knowledge could be used to suggest changes in lifestyle to help prevent AP in people who are at risk and to reduce the risk of AP or reduce its severity in people who have already had an episode of AP.

Who can participate?
1. People who have had AP in four groups relating to the possible cause of AP: gallstones, hypertriglyceridemia (high levels of fat in the blood), high alcohol intake, other (cystic fibrosis, injury, viral infection etc).
2. People who have not had AP but have one of the possible causes of AP: gallstones, hypertriglyceridemia (high levels of fat in the blood), high alcohol intake, other (cystic fibrosis, injury, viral infection etc).
3. People who are in hospital for reasons other than internal medicine disorders.
4. Healthy people who are not in hospital and have not had AP.

What does the study involve?
All participants will complete questionnaires about their socioeconomic factors (for example income level, social standing) and lifestyle (including dietary habits, physical activity, stress levels and sleep quality) covering the last year and the last month. The questionnaires will take about 2 hours to complete and trained administrators will help the participants to complete them.

What are the possible benefits and risks of participating?
There are no benefits and risks in participating in this study.

Where is the study run from?
The University of Pécs Medical School Institute for Translational Medicine (Hungary).

When is the study starting and how long is it expected to run for?
August 2018 to June 2026

Who is funding the study?
The University of Pécs, Medical School

Who is the main contact?
Andrea Szentesi, Study Coordinator, Institute for Translational Medicine, Medical School, University of Pécs
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
V1

Study information

Scientific Title
LIFEStyle, Prevention and risk of Acute paNcreatitis (LIFESPAN): Protocol of a prospective, multicentre and multinational observational case-control study

Acronym
LIFESPAN

Study objectives
The main goal of our study is to determine negative or positive associations between socio-economic factors, dietary habits, physical activity, chronic stress and sleep quality and acute pancreatitis. This would enable us to suggest lifestyle modifications for patients discharged from the hospitals after AP or for those who wish to reduce their risk for AP.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 31/10/2018, Secretary of Medical Research Council Scientific and Research Ethics Committee (Pf.: 314., Budapest, 1903, Hungary; +36 1 795-1197; tukeb@bm.gov.hu), ref: 54175-2/2018/EKU

Study design
Prospective observational multicentre case-control study.

Primary study design
Observational

Study type(s)
Prevention

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

Interventions
LIFESPAN is an observational study, therefore there is no intervention performed. Participants who fulfill the inclusion criteria will be asked to spend approximately 2 hours answering a complex questionnaire about their lifestyle and medical history. The questions cover eating and sleeping habits, physical activity, stress levels and socioeconomic status. We are going to ask the same questions concerning the last year and the last month. There is no follow-up in this study. The applied questionnaires are validated. Trained administrators will help the participants to complete them.
Every patient suffering from AP will have the opportunity to take part in the case group of the study. According to the etiology of the AP (alcoholic, biliary, hypertriglyceridemia or other), four subgroups will be formed. The four subgroups will be matched with the following control groups: (a) patients with alcoholic or biliary or hypertriglyceridemia background with no AP, (b) patients suffering from acute diseases other than internal medicine associated diseases and (c) healthy subjects.

Intervention Type
Behavioural

Primary outcome(s)
1. Personal details and physical and socioeconomic status assessed using questions from the National Health and Nutrition Examination Survey (NHANES 2015-16), the American Community Survey (ACS) and the MacArthur Scale of Subjective Social Status.
2. Medical history assessed using the Acute Pancreatitis Questionnaire (Registry for Pancreatic Patients by Hungarian Pancreatic Study Group).
3. Dietary habits assessed using the Diet History Questionnaire, Version 2.0.
4. Physical activity assessed using the International Physical Activity Questionnaire (IPAQ, long, usual-week version) .
5. Stress levels assessed using the Perceived Stress Scale (10-item version).
6. Sleep quality assessed using the Pittsburgh Sleep Quality Index.
All these questionnaires were completed on the day of recruitment. Participants filled in two of each questionnaire - one covering the last year and one covering the last month.

7. Characteristics of acute AP assessed using the Acute Pancreatitis Questionnaire was filled out once by the AP participants only.

Key secondary outcome(s))
N/A

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Patients with acute pancreatitis (AP):
1. Aged over 18 years
2. Diagnosed AP on the basis of the “2 out of 3” rules 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
3. Written informed consent form is signed.

Patients with AP in alcohol etiology group:
4. Patients consuming >5 drinks per day or >35 drinks per week for both sexes [= 8.75 units per day; 61.25 units per week] shall be included. Please note that 1 unit of alcohol = 10 ml or 8 g of pure (100%) alcohol.

Patients with AP in gallstone etiology group:
5. Presence of gallstone (not sludge).

Patients with AP in hypertriglyceridemia etiology group:
6. Triglyceride level in blood over 11 mmol/l.

Patients with AP in ‘other’ etiology group:
7. The causative agents do not match either of the first 3 groups, AP is induced by e.g.: endoscopic retrograde cholangiopancreatography (ERCP) (post-ERCP pancreatitis), virus infection, trauma, medicine (drug-induced pancreatitis), congenital anatomical malformation, cystic fibrosis, genetics, gluten sensitive enteropathy etc.

Control groups (Patients with no AP history):
8. Aged over 18 years
9. Absence of AP at present as well as in the medical history
10. Written informed consent form is signed

Control patients in alcohol group:
11. Patients consuming >5 drinks per day or >35 drinks per week for both sexes [= 8.75 units per day; 61.25 units per week] shall be included. Please note that 1 unit of alcohol = 10 ml or 8g of pure (100%) alcohol.

Control patients in gallstone group:
12. Presence of gallstone (not sludge).

Control patients in hypertrigliceridaemia group:
13. Triglyceride level over 11 mmol/l.

Control patients in hospital-based control group:
14. Hospital admissions in Traumatology, Ophthalmic Department, etc.

15. Control patients in population-based control group

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients do not have reliable information or data.
2. Patients unlikely to adhere to study requirements.

Date of first enrolment
01/04/2019

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Hungary

Romania

Study participating centre
Institute for Translational Medicine, Medical School, University of Pécs
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Study participating centre
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Study participating centre
University of Debrecen
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Study participating centre
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Study participating centre
Institute of Pancreatic Diseases, Semmelweis University
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Study participating centre
County Emergency Clinical Hospital of Târgu Mures - Gastroenterology Clinic and University of Medicine, Pharmacy, Sciences and Technology "George Emil Palade"
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Sponsor information

Organisation

University of Pécs Medical School, Momentum Grant of the Hungarian Academy of Sciences

Organisation
Economic Development and Innovation Operative Programme Grant and Highly Cited Publication Grant of the National Research, Development and Innovation Office

Organisation
Translational Medicine Foundation

Organisation
Hungarian Academy of Sciences

ROR
https://ror.org/02ks8qq67

Funder(s)

Funder type
University/education

Funder Name
Általános Orvostudományi Kar, Pécsi Tudományegyetem

Alternative Name(s)
Medizinische Fakultät, Universität Pécs, PTE Általános Orvostudományi Kar, Medizinische Fakultät, Universität Pécs, Medical School, University of Pécs, ÁOK, PTE, UP MS, PTE ÁOK

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Hungary

Results and Publications

Individual participant data (IPD) sharing plan

The study data will be available upon request from the principal investigator (Prof. Péter Hegyi, Institute of Translational Medicine, University of Pécs, Medical School, hegyi.peter@pte.hu). The questionnaires, the eCFR (raw data) and the analyzed data can be available for other laboratories' reasonable use following a personal request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		06/01/2020	05/01/2024	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes