

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

Submission date 15/10/2018	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/01/2019	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/01/2024	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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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Study website
www.tm-centre.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Prevention

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

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 measure

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.

Secondary outcome measures

N/A

Overall study start date

01/08/2018

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 hypertriglyceridaemia 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

3900, including 1700 patients in the AP group and 2200 subjects in the control groups

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

Szigeti út 12.

Pécs

Hungary

H-7624

Study participating centre

Department of Medicine, University of Szeged

Kálvária sgt. 57

Szeged

Hungary

H-6725

Study participating centre

University of Debrecen

Egyetem tér 1.

Debrecen

Hungary

H-4032

Study participating centre

Szent György Teaching Hospital of Fejér County

Seregélyesi u. 3.

Székesfehérvár

Hungary

H-8000

Study participating centre

Institute of Pancreatic Diseases, Semmelweis University

Tömő u. 25-29

Budapest

Hungary

H-1083

Study participating centre

County Emergency Clinical Hospital of Târgu Mures - Gastroenterology Clinic and University of Medicine, Pharmacy, Sciences and Technology "George Emil Palade"

Strada Gheorghe Marinescu 50

Targu Mures

Romania

540136

Sponsor information

Organisation

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

Sponsor details

LP2014-10/2014

Pécs

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Sponsor type

University/education

Organisation

Economic Development and Innovation Operative Programme Grant and Highly Cited

Publication Grant of the National Research, Development and Innovation Office

Sponsor details

GINOP-2.3.2-15-2016-00048 'Stay Alive', KH-125578 and EFOP 3.6.2-16-2017-00006 'Live Longer'

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Sponsor type

Government

Organisation

Translational Medicine Foundation

Sponsor details

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Sponsor type

Hospital/treatment centre

Organisation

Hungarian Academy of Sciences

Sponsor details

-
-
Hungary
-

Sponsor type

Government

Website

<http://mta.hu/english/>

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

Publication and dissemination plan

We plan to publish the results in a Q1 high-quality international journal.

Intention to publish date

30/06/2026

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