

Pain in early phase of pediatric pancreatitis (PINEAPPLE)

Submission date 27/01/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/02/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/03/2023	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The incidence of pancreatitis in children has increased in the past 10 years and the reasons are unclear. According to the two major studies in the USA and Australia, 3.6 and 13.2 children in 100,000 have the disease, which proves that pancreatitis is not rare among children. A retrospective trial in Pittsburgh, Pennsylvania (USA), suggests a close relation between the number of serum amylase and lipase measurements and the rising incidence of the disease, which suggests that pancreatitis in children is an underdiagnosed disease. The aim in this study is to explore the path from the first sign of abdominal pain to the diagnosis of pancreatitis.

Who can participate?

Children with abdominal pain attending the emergency department of a hospital.

What does the study involve?

Patients will be followed up until the diagnosis of pancreatitis.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

1. University of Szeged (Hungary)
2. Leipzig University (Germany)

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

February 2015 to March 2020

Who is funding the study?

Hungarian Pancreatic Study Group (Hungary)

Who is the main contact?

Dr Peter Hegyi
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Study website

<http://pancreas.hu/en/studies/pineapple>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Pain IN EARly phase of Pediatric Pancreatitis (PINEAPPLE) trial: a cohort study

Acronym

PINEAPPLE

Study objectives

1. To explore the route from the first sign of abdominal pain to the diagnosis of pancreatitis in a retrospective (PINEAPPLE-R) and prospective (PINEAPPLE-P) data collection methods:
1.1. PINEAPPLE-R: to look into the diagnostical practice by overviewing 1-month patient flows of medical and surgical emergency units
1.2. PINEAPPLE-P: to provide a fast, simple and authentic scoring system that helps to evaluate (in a reliable and cost-efficient way) the necessity of pancreatic enzyme test and abdominal ultrasonography or computed tomography when a child has abdominal pain

2. Hypothesis: the number of serum amylase and lipase measurements correlate with the incidence of the disease; the assumption is that the incidence will decrease from western to eastern Europe

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Hungarian Ethical Authority (ETT TUKEB), 26/11/2014, no. 52857-3/2014

Study design

Multicentre observational clinical study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

PINEAPPLE is a clinical trial, which we welcome your institute to join. The trial protocol aims to explore the route from the first sign of abdominal pain to the diagnosis of pancreatitis in a retrospective (PINEAPPLE-R) and a prospective (PINEAPPLE-P) way. There is little information available in publications on pediatric pancreatitis. According to the two major studies in the USA and Australia surveying the incidence of pediatric pancreatitis, 3.6 and 13.2 in 100.000 children have the disease, which proves that pancreatitis is not a rare disease among children. The incidence of pediatric pancreatitis has increased in the past 10 years and the reasons are unclear yet. A retrospective trial in Pittsburgh (USA) suggests a close relation between the number of serum amylase and lipase measurements and the incidence of the disease, which raises the possibility of pediatric pancreatitis being an underdiagnosed disease. Pediatric pancreatitis is an especially rarely diagnosed disease in Central and Eastern Europe. The aim of this trial is to retrospectively look into our diagnostical practice (PINEAPPLE-R), and to provide a fast, simple and authentic value system that helps to evaluate (in a reliable and cost efficient way) the necessity of pancreatic enzyme test and abdominal ultrasonography or computed tomography when a child has abdominal pain. We initiated our prospective trial (PINEAPPLE-P) to accurately measure these parameters.

Health condition(s) or problem(s) studied

Alarming signs of pancreatitis

Interventions

No interventions

Intervention Type

Other

Primary outcome measure

Scoring system to evaluate (in a reliable and cost efficient way) the necessity of pancreatic enzyme testing and abdominal ultrasonography or computed tomography when a child has abdominal pain: patient data will be assessed every 3 months, with investigation of what are the most common clinical characteristics (including anamnestic information, vomiting, localisation /intensity of pain, fever and body-mass index) for acute pancreatitis.

Secondary outcome measures

N/A

Overall study start date

01/02/2015

Completion date

31/03/2021

Eligibility**Key inclusion criteria**

1. Abdominal pain
2. Age < 18 years old
3. Attending hospital emergency department

Participant type(s)

Patient

Age group

Child

Upper age limit

18 Years

Sex

Both

Target number of participants

20,000

Key exclusion criteria

1. No abdominal pain
2. Age > 18 years old

Date of first enrolment

15/02/2015

Date of final enrolment

31/12/2020

Locations

Countries of recruitment

Belarus

Bosnia and Herzegovina

Czech Republic

Estonia

Finland

Germany

Hungary

Italy

Latvia

Moldova

Poland

Romania

Russian Federation

Serbia

Slovakia

Slovenia

Spain

Sweden

Türkiye

Ukraine

United Kingdom

United States of America

Study participating centre

University of Szeged

Koranyi fasor 8-10

Szeged
Hungary
H6720

Study participating centre

Leipzig University

Liebigstrasse 20

Leipzig

Germany

D-04103

Sponsor information

Organisation

Hungarian Academy of Sciences

Sponsor details

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Sponsor type

Research organisation

Website

<http://mta.hu/>

ROR

<https://ror.org/02ks8qq67>

Funder(s)

Funder type

Research organisation

Funder Name

Hungarian Pancreatic Study Group

Results and Publications

Publication and dissemination plan

Planned publication in international scientific journals. The prestudy protocol was published in December 2016 in Digestion: <https://www.ncbi.nlm.nih.gov/pubmed/26641250>

Intention to publish date

31/12/2021

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/06/2015		Yes	No
Protocol article	protocol	01/04/2016		Yes	No
Abstract results	OP 122	01/10/2018	08/03/2023	No	No
Abstract results	OP287	01/10/2019	08/03/2023	No	No
Poster results	P1526	01/10/2019	08/03/2023	No	No