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Pain in early phase of pediatric pancreatitis (PINEAPPLE)

Submission date	Recruitment status	[X] Prospectively registered
27/01/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/02/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/03/2023	Nutritional, Metabolic, Endocrine	

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

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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
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D-04103

Sponsor information

Organisation
Hungarian Academy of Sciences

Sponsor details
SZTE MTA Lendulet Translational Gastrointestinal Research Group
8-10 Koranyi fasor
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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