

# Pain in early phase of pediatric pancreatitis (PINEAPPLE)

<b>Submission date</b> 27/01/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 12/02/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/03/2023	<b>Condition category</b> 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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# Contact information

## Type(s)

Scientific

## Contact name

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# Additional identifiers

## Protocol serial number

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 overiewing 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

**Study type(s)**

Diagnostic

**Health condition(s) or problem(s) studied**

Alarming signs of pancreatitis

**Interventions**

No interventions

**Intervention Type**

Other

**Primary outcome(s)**

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.

**Key secondary outcome(s)**

N/A

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Upper age limit**

18 years

**Sex**

All

**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**

United Kingdom

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 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

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## **Sponsor information**

**Organisation**

Hungarian Academy of Sciences

**ROR**

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

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Hungarian Pancreatic Study Group

# Results and Publications

## 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?
<a href="#">Protocol article</a>	protocol	01/06/2015		Yes	No
<a href="#">Protocol article</a>	protocol	01/04/2016		Yes	No
<a href="#">Abstract results</a>	OP 122	01/10/2018	08/03/2023	No	No
<a href="#">Abstract results</a>	OP287	01/10/2019	08/03/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Poster results</a>	P1526	01/10/2019	08/03/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes