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# Analysis of Pediatric Pancreatitis - APPLE trial

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| **Submission date**<br>27/01/2015 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>12/02/2015 | **Overall study status**<br>Completed | |
| **Last Edited**<br>07/01/2020 | **Condition category**<br>Nutritional, Metabolic, Endocrine | |

## Plain English summary of protocol

Background and study aims
In the past few years, the incidence of pancreatitis in children has risen. The assessment of severity is crucial for the management of the disease. The available scoring systems to predict severity in adults have limitations when applied to children. Early recognition of severe disease might prevent serious adverse events and improve management and overall outcome for patients. The aim in this study is to establish a simple, easy and accurate clinical scoring system for early prediction of acute pancreatitis in children.

Who can participate?
Children presenting with pancreatitis in the emergency department of a hospital

What does the study involve?
Simple potential prognostic parameters will be obtained at admission (or not later than 6–12 hours afterwards) from children diagnosed with acute pancreatitis to assess their correlation with the disease severity.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
University of Szeged (Hungary) and Leipzig University (Germany)

When is the study starting and how long is it expected to run for?
February 2015 to February 2018

Who is funding the study?
Hungarian Pancreatic Study Group (Hungary)

Who is the main contact?
Andrea Párniczky MD, PhD
andrea.parniczky@gmail.com

## Study website

http://pancreas.hu/en/studies/apple

# Contact information

### Type(s)
Scientific

### Contact name
Dr Andrea Párniczky

### Contact details
University of Szeged, First Department of Medicine
Koranyi fasor 8-10
Szeged
Hungary
H-6720
+36703751031
andrea.parniczky@gmail.com

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
Analysis of Pediatric Pancreatitis (APPLE): a cohort study

### Acronym
APPLE

### Study objectives
1. New clinical methods are needed to help improve the accuracy of early evaluation of the severity of acute pancreatitis in children. With early recognition of severe disease, doctors might have more opportunities to intervene to prevent serious adverse events and improve the overall clinical outcome. The available scoring systems to predict severity of acute pancreatitis in adults have limitations when applied to children. DeBanto or pediatric acute pancreatitis score has a low sensitivity and is not useful for the calculation of the scores at hospitalization.
2. The APPLE trial (prospective and retrospective analysis) is designed to develop a simple and accurate clinical scoring system to stratify children with acute pancreatitis during the first 6–12 hours of hospitalization according to their risk of a severe disease course, specify the genetic background and recognize better the course of pediatric pancreatitis.

### Ethics approval required

Old ethics approval format

## Ethics approval(s)
National Hungarian Ethical Authority (ETT TUKEB), 26/11/2014, no. 52499-3/2014

## Study design
Multicenter cohort study

## Primary study design
Observational

## Secondary study design
Cohort study

## Study setting(s)
Hospital

## Study type(s)
Diagnostic

## Participant information sheet
The multicenter, clinical APPLE study is aimed at pediatric patients with pancreatitis. The study protocol is suitable for tracking both newly diagnosed (APPLE-P, prospective analysis) and earlier episodes (APPLE-R, retrospective analysis) of pancreatitis. There is little information available on pediatric pancreatitis. The incidence of pediatric pancreatitis has increased in the past 10 years. According to our current knowledge, the occurrence of genetic risk factors in pediatric pancreatitis could be significantly, even 10 times higher, than in adults. Also, we know that the role of alcohol is insignificant in etiology. Children having acute pancreatitis are probably going to have recurrent episodes that eventually may lead to chronic pancreatitis. Except for etiology, we have little information on the development of the disease and its effect on life quality. The early assessment of severity is crucial in the management of the disease. Current methods of risk stratification have a limited value, as they are difficult, mainly based on invasive measurement techniques and provide relatively little additional information, thus may delay appropriate management. There is a need for new clinical methods that help to improve the accuracy of early evaluation of severity in acute pancreatitis. We assume, with early recognition of severe disease, doctors will have more possibilities to intervene to prevent serious adverse events and improve the overall clinical outcome. You can help in getting to know the disease better by joining the APPLE study.

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

## Interventions
No interventions

## Intervention Type
Other

## Primary outcome measure
1. Develop a simple and accurate clinical scoring system to stratify children with acute pancreatitis during the first 6–12 hours of hospitalization according to their risk of a severe

disease course: simple data (e.g. medical history, physical examination, laboratory tests and diagnostic imaging ) will be collected, recorded and statistically analyzed to assess their potential correlation with the disease severity
2. Specify the genetic background: mutations in the genes PRSS1, CTRC, CPA1, CFTR and SPINK1 will be sequenced
3. Recognize better the course of the pediatric pancreatitis

Data will be analyzed at 3 months.

### Secondary outcome measures
N/A

### Overall study start date
01/02/2015

### Completion date
31/03/2022

## Eligibility

### Key inclusion criteria
1. Acute pancreatitis
2. Age < 18 years old
3. Presenting at the emergency department of a hospital

### Participant type(s)
Patient

### Age group
Child

### Upper age limit
18 Years

### Sex
Both

### Target number of participants
300

### Key exclusion criteria
Age > 18 years old

### Date of first enrolment
15/02/2015

### Date of final enrolment
31/12/2021

## 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
H-6720

**Study participating centre**
**Leipzig University**
Liebigstrasse 20
Leipzig
Germany
D-04103

# Sponsor information

**Organisation**
Hungarian Academy of Sciences

**Sponsor details**
SZTE MTA Lendulet Translational Gastrointestinal Research Group
8-10 Koranyi fasor
Szeged
Hungary
H-6720
+3662545200
hegyi.peter@med.u-szeged.hu

**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

International Scientific Journals The prestudy protocol was published in November 2016 in Digestion:
https://www.ncbi.nlm.nih.gov/pubmed/26613586

## Intention to publish date

31/05/2022

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 01/06/2016 | | Yes | No |