# Analysis of Pediatric Pancreatitis - APPLE trial

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

#### 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

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# 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

Acute pancreatitis
 Age < 18 years old</li>
 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

<b>Countries of recruitment</b> 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
<b>Study participating centre University of Szeged</b> 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