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Analysis of Pediatric Pancreatitis - APPLE trial

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	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/01/2020	Nutritional, Metabolic, Endocrine	[_] Record updated in last year

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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Diagnostic

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

Interventions
No interventions

Intervention Type
Other

Primary outcome(s)
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.

Key secondary outcome(s))
N/A

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

Healthy volunteers allowed
No

Age group
Child

Upper age limit
18 years

Sex
All

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
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
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Study participating centre
Leipzig University
Liebigstrasse 20
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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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes