

Early Achievable SeveritY (EASY) index for simple and accurate early risk stratification in acute pancreatitis

Submission date 13/11/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/11/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/06/2022	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Acute pancreatitis (AP) is a serious condition where the pancreas becomes inflamed over a short period of time. Assessing the severity is crucial to the management of the disease. Current methods of determining the level of risk (risk stratification) in AP have a limited value as they provide little additional information and thus may delay appropriate management. Early recognition of severe disease may prevent serious adverse events and improve patient management as well as overall clinical outcome. Our aim is to develop a simple, easy and accurate clinical scoring system that can stratify patients with AP during the first 6-12 hours of hospitalization according to their risk for severe disease course, and which can also be performed in small hospitals with limited access to diagnostic tools.

Who can participate?

Patients aged 18 to 99 hospitalized due to acute pancreatitis.

What does the study involve?

This is an observational study where information from the patients' medical history, physical examination, laboratory tests and diagnostic imaging will be evaluated. The care or services that patients receive will not be altered by the study. All patients will be treated equally, according to the recently published guidelines.

What are the possible benefits and risks of participating?

Our goal is to develop a simple and accurate clinical scoring system for patient stratification. The ability to perform earlier and simpler risk stratification may prevent serious adverse events and improve patient management as well as overall clinical outcome. Because of the characteristics of the observation study there will be no risks of participation related to the trial.

Where is the study run from?

University of Szeged (Hungary)

When is the study starting and how long is it expected to run for?
December 2014 to May 2024 (updated 03/01/2020, previously: November 2017)

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

Who is the main contact?
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Study website
<http://www.pancreas.hu>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
N/A

Study information

Scientific Title
Early Achievable SeveritY (EASY) index for simple and accurate early risk stratification in acute pancreatitis: an observational multicenter prospective cohort study

Acronym

EASY

Study objectives

Acute pancreatitis is one of the most common diseases of the gastrointestinal tract that requires acute hospitalization and despite the special care is still associated with significant morbidity and mortality worldwide. The assessment of severity is a crucial issue in the management of acute pancreatitis. It is critical to identify patients who are at high risk for severe disease course, since they require close monitoring and immediate aggressive treatment.

Early recognition of severe acute pancreatitis by a simple, easy and accurate clinical scoring system for early prognostication of the disease may prevent serious adverse events and improve patient management as well as overall clinical outcome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The National Hungarian Ethical Authority (ETT TUKEB), No. 30595-1/2014/EKU

Study design

Observational multicenter prospective cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Acute pancreatitis

Interventions

The web-based Hungarian National Pancreas Registry would provide the background for data management of this trial. Simple attainable potential prognostic parameters from medical history, physical examination, laboratory tests and diagnostic imaging obtained at admission from patients diagnosed with acute pancreatitis will be evaluated to assess their potential correlation with the disease severity. The selected parameters that show the strongest correlation with severe disease course will be further utilized as potential early severity

prognostic markers for prospective new patient stratification. The comparison of patients clinical course with the obtained results of early risk stratification in case of correlation may validate the utilized parameters as prognostic markers.

Intervention Type

Other

Primary outcome measure

Validation of previously selected parameters that showed the strongest correlation with severe disease course as prognostic markers to develop a simple, easy and accurate clinical scoring system that can stratify patients with acute pancreatitis during the first 6-12 hours of hospitalization according to their risk for severe disease course.

Secondary outcome measures

N/A

Overall study start date

01/12/2014

Completion date

31/05/2024

Eligibility

Key inclusion criteria

Patients (men and women aged 18 to 99 years) hospitalized due to acute pancreatitis diagnosed based on the fulfillment of two out of three of the criteria irrespectively of the etiology

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

99 Years

Sex

Both

Target number of participants

1200

Total final enrolment

1184

Key exclusion criteria

N/A

Date of first enrolment

01/12/2014

Date of final enrolment

30/01/2024

Locations

Countries of recruitment

Hungary

Study participating centre

University of Szeged

1st Department of Medicine

Szeged

Hungary

6720

Sponsor information

Organisation

Hungarian Pancreatic Study Group (HPSG)

Sponsor details

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Sponsor type

Research organisation

Website

<http://www.pancreas.hu>

Funder(s)

Funder type

Research organisation

Funder Name

The Hungarian Pancreatic Study Group (HPSG)

Results and Publications

Publication and dissemination plan

The prestudy protocol was published in June 2015 in the Journal of Gastrointestinal and Liver Diseases:

<http://jgld.ro/2015/2/12.pdf>

Intention to publish date

31/05/2025

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/06/2015		Yes	No
Results article		01/06/2022	08/06/2022	Yes	No