

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

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

## 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?  
Balázs Kui, MD, PhD  
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## Contact information

### Type(s)

Scientific

### Contact name

Dr Balázs Kui

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

### **Study type(s)**

Diagnostic

### **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(s)**

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.

### **Key secondary outcome(s))**

N/A

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

99 years

**Sex**

All

**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)

## Funder(s)

### Funder type

Research organisation

### Funder Name

The Hungarian Pancreatic Study Group (HPSG)

## Results and Publications

### 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?
<a href="#">Results article</a>		01/06/2022	08/06/2022	Yes	No
<a href="#">Protocol article</a>	protocol	01/06/2015		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes