

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

Initiated by the Hungarian Pancreatic Study Group

SUMMARY: Acute pancreatitis (AP) is one of the most common diseases of the gastrointestinal tract associated with significant morbidity and mortality. The assessment of severity is crucial in the management of the disease. Current methods of risk stratification in AP have a limited value, as they provide little additional information 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. The **EASY** trial is an **observational, multicenter, prospective cohort study** for establishing a simple, easy and accurate clinical scoring system for early prognostication of AP. Evaluation of simple attainable potential prognostic parameters obtained **at admission (or not later than 6-12 hours afterwards)** from patients diagnosed with AP will be performed 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. Comparison of patients' clinical course with the obtained results of early risk stratification may validate the utilized parameters as prognostic markers.

CENTRES: The study is open for all centres which can provide valuable and precise data for the study. Centres can apply by filling in the "Letter of Intent to Join the **EASY** research project" (Form-J). The scientific board of HPSG keeps the right to accept/decline the application.

AUTHORSHIP POLICY: 30 patients - 1 co-author

PROTOCOL:

In order to examine/question patients right after hospitalization, it is important to co-operate with your colleagues working at the **EMERGENCY ADMISSIONS UNIT**.

Study protocol:

- 1) The institution needs to fill out and sign the "**Letter of Intent to Join the EASY research project**" and send it back to hpsg.info@gmail.com in a pdf format.
- 2) The patient needs to be informed and the "**Informed consent form**" needs to be signed. Please keep the signed informed consent forms at the place of the examination so as to be able to provide them upon request of inspection.
- 3) The "**FORM-A Questionnaire**" needs to be filled out **AT ADMISSION** according to the data of the patient. It is important to do all necessary examinations and answer all the questions, therefore, please look thoroughly through all the questions in advance.
- 4) Every day of the hospitalization the "**FORM-B Questionnaire**" needs to be filled out.
- 5) Please upload data onto www.pancreas.hu website choosing Studies/Current Studies/EASY, clicking on the EASY Login logo (login or register).

ETHICAL ISSUES:

This is an observational prospective cohort study (in which the care or services that patients receive will not be altered), therefore has a relatively low-risk. The study has an ethical approval by the National Hungarian Ethical Authority. Study management will strictly follow the Ethical Guidelines for Observational Studies.

Ethical approval number: ETT TUKEB ad. 30595/2014

Registration number: ISRCTN10525246

SHOULD YOU NEED FURTHER INFORMATION PLEASE CONTACT US!

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