

**TRIAL
PROTOCOL****Pediatric
Pancreatitis**

Dear Colleagues!

We would like to draw your attention to the multicenter, clinical **APPLE** study aimed at pediatric patients with pancreatitis. The study protocol is suitable for tracking both newly diagnosed (**APPLE-P**, prospective study) and earlier episodes (**APPLE-R**, retrospective study) of pancreatitis.

There is little information available on pediatric pancreatitis. The incidence of pediatric pancreatitis has increased in the last 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 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-P** and **APPLE-R** studies.

APPLE-R Study

Patients who had acute episode(s) earlier and are currently not in active stage can be involved in the APPLE-R study. It is important that the first pancreatitis episode should be before the age of 18 years. The study primarily provides information on possible genetic variants behind the disease and their impact on the prognosis.

For those patients who did not have genetic analysis before, we do it for free in the frame of the study. Participating patients and doctors can access the results of the analysis upon request (following the XXI./2008. Law of the Parliament). You can download the form from the www.pancreas.hu website.

Study Protocol

- 1) The institution needs to fill out and sign the “**Letter of Intent to Join the APPLE research project**” and send it back to hpsg.info@gmail.com in pdf format.
- 2) The patient needs to be informed and the “**APPLE-R Informed consent form**” needs to be signed.
- 3) The “**APPLE-R FORM-A Questionnaire**” needs to be filled out.
- 4) The blood for laboratory parameters has to be drawn (2 EDTA tubes) and stored at -20°C until delivery to the Biobank in Szeged.
- 5) Blood samples need to be delivered to Szeged. Please keep the signed informed consent forms at the place of the examination so as to be able to provide upon request of inspection.
- 6) In case the patient or you require information on the result of the genetic analysis, please let us know and we will inform you concerning the results.
- 7) Please upload data onto www.pancreas.hu website choosing Studies/Current Studies/APPLE, clicking on the APPLE logo (login or register).

JOINT PROJECT ORGANIZED BY THE HUNGARIAN PANCREATIC STUDY GROUP AND THE INTERNATIONAL ASSOCIATION OF PANCREATOLOGY



www.pancreas.hu

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www.internationalpancreatology.org

**TRIAL
PROTOCOL****Pediatric
Pancreatitis****APPLE-P Study**

Newly diagnosed patients currently in active stage and under the age of 18 years can be involved in the **APPLE-P** study. This study primarily aims to understand the development of the disease and to identify the early risk factors. Therefore, the detailed examination at the first appearance of the patient is crucial and cannot be made up for later. Please, have a thorough look at the questionnaire in advance so as to provide all the necessary data. 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 APPLE research project**” and send it back to hpsg.info@gmail.com in pdf format. In case you have already completed it for the **APPLE-R** study, you do not have to repeat it.
- 2) The patient needs to be informed and the “**APPLE-P Informed consent form**” needs to be signed.
- 3) The “**APPLE-P FORM-A Questionnaire at admission**” needs to be filled out according to the data of the patient.
- 4) Every day of the hospitalization the “**APPLE-P FORM-B Questionnaire daily**” needs to be filled out.
- 5) The blood for laboratory parameters has to be drawn (2 EDTA tubes) and stored at -20°C until delivery to the Biobank in Szeged.
- 6) Blood samples need to be delivered to Szeged. 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.
- 7) In case the patient requires information on the result of the genetic analysis, please contact us.
- 8) After the discharge of the patient, please upload data onto www.pancreas.hu website choosing Studies/Current Studies/APPLE, clicking on the APPLE logo (login or register).

CENTRES: The study is open for all centres that can provide valuable and precise data for the study. Centres can apply by filling out, signing and sending the “**Letter of Intent to Join the APPLE research project**”. The scientific board of HPSG reserves the right to accept/decline the application.

AUTHORSHIP POLICY: For APPLE-P and/or APPLE-R studies: 5 patients - 1 co-author

QUESTIONNAIRES, FORMS: Questionnaires and forms are available on the www.pancreas.hu website.

ETHICAL ISSUES:

This is an observational study that will not alter the care and services that patients receive, therefore has a low risk. The study has an ethical approval by the National Hungarian Ethical Authority (ETT TUKEB). Study management will strictly follow the Ethical Guidelines for Observational Studies.

Ethical approval number: ETT TUKEB ad.52499-3/2014 and ad.22254-1/2012

Registration number: ISRCTN89664974

Your questions and comments are welcome at the below contact details.

Péter Hegyi
HPSG Chair

Andrea Párniczky
Principal Investigator

Szeged, 30th September 2014

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