

TRIAL Pediatric PROTOCOL Pancreatitis



PINEAPPLE

Dear Colleagues!

We would like to draw your attention to the multicenter, clinical trial **PINEAPPLE**, which we welcome your institute to join. The trial protocol aims to explore the route from the first sign of abdominal pain to the diagnosis of pancreatitis in a retrospective (**PINEAPPLE-R**) and prospective (**PINEAPPLE-P**) way.

There is little information available in publications on pediatric pancreatitis. According to the two major studies in the United States and Australia surveying the incidence of pediatric pancreatitis, 3.6 – 13.2 in 100.000 children have the disease, which proves that pancreatitis is not a rare disease among children. The incidence of pediatric pancreatitis has increased in the last 10 years and the reasons are unclear yet. A retrospective trial in Pittsburgh suggests close relationship between the number of serum amylase and lipase measurement and the incidence of the disease, which raises the possibility of pediatric pancreatitis being an underdiagnosed disease. Pediatric pancreatitis is an especially rarely diagnosed disease in Central and Eastern Europe.

The aim of this trial is to retrospectively look into our diagnostical practice (**PINEAPPLE-R**), and to provide a fast, simple and authentic value system that helps to evaluate (in a reliable and cost efficient way) the necessity of pancreatic enzyme test and abdominal ultrasonography or CT when a child has abdominal pain. We initiated our prospective trial (**PINEAPPLE-P**) to accurately measure these parameters.

PINEAPPLE-R trial

In one certain month (e.g. in September 2014) we collect information on patients appearing with abdominal pain at emergency and surgical units, concerning their clinical symptoms, results of imaging examinations and laboratory parameters. The excel form can be downloaded from www.pancreas.hu (PINEAPPLE-R-ENG-FORM A.xls).

Trial protocol

1. The Institute should fill out, sign and send the **PINEAPPLE** "Letter of Intent to Join" form to the hpsg.info@gmail.com e-mail address.
2. According to patients data, the **PINEAPPLE-R** excel table (PINEAPPLE-R-ENG-FORM A.xls") should be filled in and sent. The table can be downloaded from the www.pancreas.hu website in the Studies/Active studies/PINEAPPLE menu point. (If you have any problem with providing names and insurance numbers for personal data protection reasons, please provide an individual code instead. It is important that you can identify the person by this individual code later if it is necessary for data quality inspection.)

PINEAPPLE-P trial

Patients under 18 years appearing with abdominal pain at emergency and surgical units, can be included in the trial. This trial helps to evaluate the possibility of pancreatitis as the reason behind the abdominal pain and helps to recognise it early. The detailed examination at the first appearance of the patient is very important. Please look at the questionnaire thoroughly in advance so as not to leave out any of the necessary examinations.

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Trial Protocol

1. The Institute should fill out, sign and send the **PINEAPPLE** "Letter of Intent to Join" form to the hpsg.info@gmail.com e-mail address. In case you have already filled out the form for **PINEAPPLE-R** trial, you do not need to do it again.
- 1) The patient needs to be informed and the "**PINEAPPLE-P** 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.
2. The "**PINEAPPLE-P** ENG FORM-A" needs to be filled out according to the data of the patient.
3. Measuring serum amylase and lipase level.
4. Abdominal imaging examination (ultrasonography and/or CT).
5. Please upload data onto www.pancreas.hu website choosing Studies/Current Studies/PINEAPPLE, clicking on the **PINEAPPLE** logo (login or register).

CENTRES: The study is open for all pediatric centres with emergency admissions that can provide valuable and precise data for the study. Centres can apply by filling out, signing and sending the **PINEAPPLE** "Letter of Intent to Join" form.

AUTHORSHIP POLICY:

PINEAPPLE-R: under 1500 patients - 1 co-author, above 1500 patients – 2 co-authors.
PINEAPPLE-P: 100 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. This study has an ethical approval by the National Hungarian Ethical Authority.

Etichal approval number: ETT TUKEB ad.52857-2/2014
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Your questions and comments are welcome at the below contact details.

Péter Hegyi
HPSG Chair
Tel: +36 70 375 1031
e-mail: hegyi2009@gmail.com

Dóra Mosztbacher
Principal Investigator
Tel: +36 20 984 0776
e-mail: dora.mosztbacher@gmail.com

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