

Protocol and early results of a prospective clinical trial in pediatric pancreatitis (PINEAPPLE-P - Pain IN the EARly phase of Pediatric Pancreatitis).

Tóth A.¹, Mosztbacher D.², Zsoldos F.³, Szentesi A.⁴, Tóth G.², Bereczki Cs.¹ és Hegyi P.^{4,5}, on behalf of the Hungarian Pancreatic Study Group.

¹University of Szeged, Faculty of Medicine, Department of Pediatrics and Pediatric Health Center, ²János Balassa County Hospital, Department of Pediatrics, Szekszárd, ³Heim Pál Children's Hospital, Budapest, ⁴University of Szeged, Faculty of Medicine, First Department of Medicine, ⁵Hungarian Academy of Sciences - University of Szeged, Momentum Gastroenterology Multidisciplinary Research Group

Background: The reported incidence of pediatric pancreatitis is low, however, the disorder is likely underdiagnosed. Retrospective data analyses (PINEAPPLE-R) suggest that pancreatic enzyme (amylase or lipase) measurements (PEM) are ordered only for a small number of children presenting with abdominal pain in emergency units. Currently no evidence based (EBM) guideline is available to offer proper instructions concerning the necessity of PEM in children.

Aim: Our aim is to develop a fast and reliable scoring system based on multicenter, multinational prospective data collection, which can help to decide the necessity of PEM in children with abdominal pain.

Methods: Patients under 18 years with abdominal pain are included. The detailed protocol contains questionnaire concerning child medical history, complaints, symptoms especially concerning the characteristics of abdominal pain. Proper physical examination including evaluation of abdominal tenderness and guarding is performed. PEM and abdominal imaging are performed in all cases. The trial has been internationally discussed and registered at the ISRCTN registry (ISRCTN35618458). Data can be collected via an electronic data administration system. <http://pancreas.hu/en/studies/pineapple>

Results: 59 children with abdominal pain have been enrolled into the study within a month and one case of pancreatitis has already been discovered. The duration of the abdominal pain was 4 days before diagnosis. The pain was cramping, continuous, localized to the epigastrium. Both lipase and amylase levels were elevated more than 3 times above the normal level. Transabdominal ultrasound examination showed no alteration in the pancreas.

Conclusion: This trial will help to develop an EBM guideline. More centres/patients are required.