

# Is early energy supply to patients suffering from acute pancreatitis beneficial?

<b>Submission date</b> 08/11/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/01/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/01/2020	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Acute pancreatitis is a serious condition where the pancreas becomes inflamed over a short period of time. Treatment usually involves admission to hospital where a feeding tube is inserted through the nose and into the stomach to provide patients with nutrients. This is known as enteral feeding. The aim of this study is to find out whether starting enteral feeding early is beneficial to patients with acute pancreatitis.

### Who can participate?

Patients aged over 18 with acute pancreatitis

### What does the study involve?

Participants are randomly allocated to one of two groups. Group A receives enteral feeding within 24 hours of admission to hospital. Group B receives no enteral feeding in the first 24 hours of hospital admission. Intravenous glucose (given into a vein) or total parenteral nutrition (all nutrients given directly into the bloodstream) are also provided if needed. Organ failure, death rates and pancreatic necrosis (infection), length of hospital stay and pain are measured in both groups daily during the study and at 1-month follow up.

### What are the possible benefits and risks of participating?

There are no risks involved with early enteral feeding.

### Where is the study run from?

University of Pécs (Hungary)

### When is the study starting and how long is it expected to run for?

January 2017 to January 2020

### Who is funding the study?

University of Pécs (Hungary)

Who is the main contact?  
Prof. Peter Hegyi  
p.hegyi@tm-pte.org

**Study website**  
www.pancreas.hu

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Peter Hegyi

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
-

## Study information

**Scientific Title**  
High versus low energy administration in the early phase of acute pancreatitis: a multicentre randomized double-blind clinical trial

**Acronym**  
GOULASH

**Study objectives**  
Researchers showed that enteral feeding is beneficial compared to a nil per os diet not only in severe, but also in mild and moderate AP. This study will provide the first evidence concerning the necessity of early energy supply.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Medical Research Council – Scientific and Research Ethics Committee, 25/10/2016 - approval pending

**Study design**

Randomised controlled two-arm double-blind multicentre interventional study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

See additional files

**Health condition(s) or problem(s) studied**

Acute pancreatitis

**Interventions**

Patients suffering from acute pancreatitis are randomised by computer into two groups:

Group A: high energy administration after admission

Patients will receive a 10 Ch nasogastric (NG) or nasojejunal (NJ) feeding tube at admission

EN will immediately started as follows:

Day 0: (From admission until the start of EN (can be vary from 2-24 h)): calorie intake: 0 kcal/kg /day

Day 1: High Energy Enteral Tube Feed (1.5 kcal/ml) 30 kcal/kg/day (volume cannot exceed 60 ml /h)

Day 2: High Energy Enteral Tube Feed (1.5 kcal/ml) 30 kcal/kg/day

Day 3: until it is necessary: High Energy Enteral Tube Feed (1.5 kcal/ml) 30 kcal/kg/day

Group B: low energy administration after hospital admission

Patients will receive a 10 Ch nasogastric or nasojejunal feeding tube at admission

EN will immediately start

Day 0: (From admission until the start of EN (can be vary from 2-24 h)): calorie intake: 0 kcal/kg /day

Day 1: Zero Energy Enteral Tube Feed (0 kcal/ml) 1440 ml/day

Day 2: Step Up1 Energy Enteral Tube Feed (0.50 kcal/ml) 10 kcal/kg/day (volume cannot exceed 60ml/h)

Day 3: Step Up2 Energy Enteral Tube Feed (1.00 kcal/ml) 20 kcal/kg/day

Day 4 (if needed): Step Up3 Energy Enteral Tube Feed (1.25 kcal/ml) 25 kcal/kg/day

Day 5 (if needed): Step Up4 Energy Enteral Tube Feed (1.5 kcal/ml) 30 kcal/kg/day

Day 6 (if needed): Step Up5 Energy Enteral Tube Feed (1.5 kcal/ml) 30 kcal/kg/day

Day 7 (if needed): High Energy Enteral Tube Feed (1.5 kcal/ml) 30 kcal/kg/day

Zero Energy Enteral Tube Feed (100ml): Energy: 0 kcal (0 KJ), Protein 0g, Carbohydrate: 0g, Fat: 0g + Minerals: 134mg Sodium, 201mg Potassium, 34mg Magnesium, 4,872 g Chloride (0%E) (in this study the local institutional pharmacy will compose it in accordance with the Hungarian regulations)  
308,9 mOsm/L.

Patient is counted as discharged from hospital/from the study when:

1. The total feeding was tolerated for 24h
2. No amylase/lipase level were elevated after total feeding
3. CRP level is less than 50 mg/L
4. Abdominal pain has completely resolved
5. No other pancreatitis-related complication requiring hospitalization is detected

One follow-up visit will take place 1 month after hospital discharge.

Severity (mild, moderate, severe), mortality and pancreatic necrosis are defined as primary endpoints, whereas several secondary endpoints such as length of hospitalization or pain, are determined to understand the finer differences between the groups. The general feasibility, safety and quality checks required for the highest quality evidence are performed.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome measure**

1. Multi organ failure persisting for more than 48h, measured by clinical assessment at admission, daily during the study and at 1-month follow up
3. Mortality, measured at admission, daily during the study and at 1-month follow up

## **Secondary outcome measures**

1. Pancreatic necrosis, measured by CT at admission, daily during the study and at 1-month follow up
2. Nutrition related complications: diarrhoea, aspiration pneumonia, pneumothorax due to central TPN catheter placement, measured by clinical assessment at admission and daily during the study
3. Need for conversion from NG to NJ feeding tube, measured by clinical assessment at admission and daily during the study
4. Need for conversion from enteral nutrition (EN) to total parenteral nutrition (TPN), measured by clinical assessment at admission and daily during the study
5. Days until the start of total feeding, measured daily during the study
6. Use of antibiotics, measured daily during the study
7. Pain relapse, measured using the VAS scale daily during the study
8. C-reactive protein (CRP), measured by laboratory test daily during the study
9. White blood cell (WBC) count, measured by laboratory test daily during the study
10. Procalcitonin (PCT), measured by laboratory test daily during the study
11. Infection, measured by microbiological test daily during the study
12. Length of hospital stay, measured daily during the study
13. Need for ICU admission, measured at admission and daily during the study
14. Length of ICU therapy, measured at admission and daily during the study

- 15. Organ failure, measured at admission and daily during the study
- 16. Complications, measured at admission, daily during the study and at 1-month follow up
- 17. Costs calculation

**Overall study start date**

01/01/2017

**Completion date**

01/01/2023

## Eligibility

**Key inclusion criteria**

- 1. Patients above 18 years of age
- 2. Diagnosed with acute pancreatitis on the basis of the "2 out of 3" rule of the IAP/APA guideline
- 3. Written informed consent form is signed

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

957

**Key exclusion criteria**

- 1. Hospitalization 72 hours before admission
- 2. Abdominal pain >120 hours (5 days)
- 3. Delirium tremens
- 4. Child-Pugh C stage liver cirrhosis
- 5. AP due to malignancy
- 6. Already on artificial nutrition (enteral or parenteral nutrition)
- 7. Pregnancy
- 8. BMI above 40 or below 18
- 9. Age above 80
- 10. Ketoacidosis
- 11. Whenever CT with contrast is contraindicated

**Date of first enrolment**

01/02/2017

**Date of final enrolment**

01/12/2022

## Locations

### Countries of recruitment

Hungary

### Study participating centre

University of Pécs

Szigeti Street 12

Pécs

Hungary

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## Sponsor information

### Organisation

University of Pécs

### Sponsor details

Center for Translational Medicine

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### Sponsor type

Not defined

### Website

<http://aok.pte.hu/en/egyseg/index/150>

### ROR

<https://ror.org/037b5pv06>

## Funder(s)

### Funder type

University/education

**Funder Name**  
University of Pécs

## Results and Publications

### Publication and dissemination plan

The pre-study-protocol is planned to be published. The publication date of the results is to be confirmed at a later date.

### Intention to publish date

01/01/2024

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Péter Hegyi MD (p.hegyi@tm-pte.org).

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>		18/11/2016	15/06/2017	No	Yes
<a href="#">Protocol article</a>	protocol	14/09/2017		Yes	No