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

Submission date 08/11/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 03/01/2017	**Overall study status** Completed	
Last Edited 07/01/2020	**Condition category** Digestive System	

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
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Study website
www.pancreas.hu

Contact information

Type(s)
Scientific

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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
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Sponsor information

Organisation
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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?
Participant information sheet		18/11/2016	15/06/2017	No	Yes
Protocol article	protocol	14/09/2017		Yes	No