Pancreatitis, verY earlY compared wiTH delayed start Of eNteral feeding (PYTHON) trial: a randomised controlled multicenter trial.

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To investigate whether a very early start of EN (< 24 hrs after admission), as compared to selective delayed EN (> 72 hrs), will lead to a lower rate of infectious complications and mortality in patients with predicted severe AP.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal infections
Study type	Interventional

Summary

ID

NL-OMON35528

Source
ToetsingOnline

Brief title
PYTHON

Condition

- Gastrointestinal infections
- Bacterial infectious disorders

Synonym
pancreas infection, pancreatitis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: infection, nutrition, pancreatitis, randomized

Outcome measures

Primary outcome

The primary endpoint is the fraction of patients with an infectious

complication or mortality during hospital stay (composite endpoint).

Re-admission within 10 days after discharge is considered as one hospital

admission.

Secondary outcome

Secondary endpoints occurring during hospital admission include:

• Individual components of the primary endpoint

• Urinary tract infection (dysuria with bacteruria >10.000 CFU/mL)

• Nutrition related complications: diarrhea, aspiration pneumonia,

pneumothorax due to

central TPN catheter placement

• Need for conversion from EN to TPN

• Days until intake of solid food

• Use of antibiotics

• Pain relapse

• CRP and leukocytes as measures of systemic inflammation

• Length of hospital stay

• Need for ICU admission

• New onset organ failure (onset, extent and duration, see definitions section)

• Length of ICU stay

• Need for percutaneous drainage

• Need for surgical or endoscopical necrosectomy

• Gastrointestinal permeability measured with the PEG test

• Hand grip strength measured once per week

• Quality of life and total direct and indirect costs

• Proportion of daily nutritional target achieved at 1 week after admission.

• Number of patients without the need for tube feeding.

• Cross-over between both study arms.

Study description

Background summary

In patients with predicted severe acute pancreatitis, enteral nutrition (EN) via a feeding tube reduces the risk of infectious complications and mortality compared to total parenteral nutrition. It has been suggested that very early EN* (i.e. < 24 hours after admission) reduces morbidity and mortality as compared to the current practice of starting EN after 3-4 days when it becomes clear that the patient will be not able to eat for several days.

Study objective

To investigate whether a very early start of EN (< 24 hrs after admission), as compared to selective delayed EN (> 72 hrs), will lead to a lower rate of infectious complications and mortality in patients with predicted severe AP.

Study design

A randomised controlled parallel group superiority multicenter trial. Patients

will be randomly allocated to A) EN < 24 hours after hospital admission or B) EN after 72 hours of admission.

Intervention

Nasojejunal EN < 24 hours after admission

Study burden and risks

In the early enteral nutrition arm patients will recieve a nasojejunal feeding tube within 24 hours of hospital admission. Enteral nutrition will be started and increased to full nutrition in 48-72 hrs. If a patient will be able to eat after a few days, the feeding tube will be removed. In the late nutrition arm patients wil be evaluated after 72 hrs if they are able to eat or not. If not they will recieve a nasogastric feeding tube.

This study will imply no extra risks for the patients involved. A nasojeunal feeding tube is safe and most patients with acute pancreatitis recieve a nasojejunal feeding tube. Blood test are performed in accordance to normal testing days.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Acute pancreatitis: upper abdominal pain and serum lipase and/ or amylase levels 3 times the upper level of normal
Age 18 years or above
Written informed consent

Exclusion criteria

History of acute or chronic pancreatitis
Admitted to hospital > 24 hours (either for acute pancreatitis or for other conditions)
Symptoms > 96 hours (4 days)
Acute pancreatitis due to malignancy
Diagnosis of acute pancreatitis during operation for acute abdomen
Post ERCP pancreatitis
Already on artificial nutrition (enteral or parenteral)
Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-08-2008
Enrollment:	208
Type:	Actual

Ethics review

Approved WMO Date:	04-03-2008
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	08-07-2008
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-05-2009
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-11-2009
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-01-2010
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	19-07-2010
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-10-2010
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ISRCTN	ISRCTN18170985
CCMO	NL20057.041.07