Comparison of intragastric vs intrajejunal feeding in chronic pancreatitis; effect on abdominal symptoms

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The aim of the study is to compare the effect jejunal with that of gastric tube feeding on abdominal symptoms.

Ethical review	Approved WMO
Status	Pending
Health condition type	Exocrine pancreas conditions
Study type	Interventional

Summary

ID

NL-OMON29917

Source
ToetsingOnline

Brief title
Enteral nutrition and pain in pancreatitis

Condition

- Exocrine pancreas conditions

Synonym
chronic 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: enteral nutrition, pain, pancreatitis

Outcome measures

Primary outcome

Intensity of abdominal pain

Secondary outcome

Secondary parameters of the study are severity of other abdominal symptoms,

health related quality of life, global releave score, global evaluation of

efficacy score, concentrations of circulating gut hormones.

Study description

Background summary

Patients with chronic pancreatitis often suffer from abdominal pain which aggravates after meal ingestion. Enteral nutrition alleviates this pain in some patients. The hypothesis is that intrajejunal tube feeding is superior to intragastric tube feeding.

Study objective

The aim of the study is to compare the effect jejunal with that of gastric tube feeding on abdominal symptoms.

Study design

Double blind, randomized cross-over design.

Intervention

Intragastric and intrajejunal tube feeding.

Study burden and risks

A feeding tube will be placed by endoscopy once in the stomach and once in the

proximal jejunum. At 4 weeks and at 8 weeks the position of the tube is checked by fluoroscopy. We measure resting energy expenditure once in the screening phase by non-invasive indirect calorimetry.
A total amount of 140 mL blood will be drawn at 3 visits over a period of 10 -12 weeks. The patient keeps a diary and fills out questionnaires.

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

· Pain is aggravated by meal ingestion, at least 3 times per week in past month
· Pain most likely due to chronic pancreatitis (CP)
· Pain is daily (type B-pain)
· Pain is stable for more than 3 months
· Clinical indication for enteral feeding

· Diagnosis of chronic pancreatitis
· Age > 18 y; < 70 y
· able to read and understand the questionnaires

Exclusion criteria

· Intermittent pain with pain free days (type A pain)
· Exocrine pancreatic insufficiency
· Duodenal or choledochal stenosis
· Narcotic analgesics except tramadol
· Surgery of stomach, pancreas, duodenum or jejunum
· Jejunostomy for enteral feeding
· Instable pain medication
· No abstinence from alcohol in alcoholic CP
· Evidence that abdominal pain may not be related to feeding or may not originate from pancreas
· Other disorders of the upper gastrointestinal tract
· Liver or biliary disorders
. Contra-indication for enteral tube placement
. Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2006
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL12398.091.06