NAtural history of Peri-pancreatic cOLlEctiONs in acute pancreatitis based on assessment of content with CECT and MRI.

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Aim of this study is to investigate the natural course of early peripancreatic collections (i.e. acute fluid collections) in patients with predicted severe AP by CECT and by MRI.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Exocrine pancreas conditions
Study type	Observational non invasive

Summary

ID

NL-OMON33664

Source
ToetsingOnline

Brief title
NAPOLEON

Condition

- Exocrine pancreas conditions

Synonym
pancreatitis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CECT, collections, MRI, Pancreatitis

Outcome measures

Primary outcome

The primary endpoint is the amount of solid debris as seen on initial MRI in

relationship to the absorption rate of these collections.

Secondary outcome

• Infectious complications (bacteremia, pneumonia, infected necrosis).

• 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

• Quality of Life.

Study description

Background summary

In patients with acute pancreatitis, peripancreatic collections often occur that either spontaneous resolve or enlarge and become symptomatic. It is generally acknowledged that CECT is inadequate to discriminate accurately between collections containing fluid and collections consisting of fluid and solid debris and that MRI is better suited for making this distinction.

Study objective

Aim of this study is to investigate the natural course of early peripancreatic collections (i.e. acute fluid collections) in patients with predicted severe AP

by CECT and by MRI.

Study design

A prospective multicenter international study

Study burden and risks

De burden for the patient exists of 2 extra MRI's. These investigations are not part of everyday practice in patients with acute pancreatitis. However they are part of everyday practice in a hospital and should not imply an extra risk for the patient. However every patient that ondergoes the extra MRI scans will be followed carfully by the attending doctor or by the trial coordinator.

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

• Age 18 years or above
• Acute pancreatitis: upper abdominal pain and serum lipase and/ or amylase levels 3 times the upper level of normal
• Written informed consent
• Patients with peripancreatic fluid collections on CECT > 3 cm in short axis.

Exclusion criteria

• History or imaging signs of chronic or *acute on chronic* pancreatitis
• AP due to malignancy
• Pregnancy
• Contraindication for MRI imaging (for example pacemaker)
• Incapacitated subjects

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2009
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	22-12-2008

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-03-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL22374.100.08