Standard CONservative approach versus endoscopic Debridement in patients with symptomatic sterile Organized pancreatic necRosis (CONDOR trial): a prospective randomised controlled trial

Published: 14-01-2008
Last updated: 11-05-2024

To compare endoscopic transmural debridement with standard conservative treatment in patients with symptomatic sterile organized pancreatic necrosis in a randomized controlled trial with emphasis on extent and duration of recovery.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON32422

Source
ToetsingOnline

Brief title
CONDOR

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal therapeutic procedures

Synonym
Symptomatic strerile organized pancreatic necrosis after acute necrotizing pancreatitis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Acute necrotizing pancreatitis, Conservative, Endoscopic debridement, Sterile pancreatic necrosis

Outcome measures

Primary outcome

Extent and duration of recovery measured by the Sickness Impact Profile (SIP)

after 12 weeks.

Secondary outcome

SIP scores after 26 and 52 weeks, total out of hospital days, resolution and

recurrence of the pancreatic fluid collection, intervention-related

complications, mortality, total number of interventions, endocrine and exocrine

function and (in)direct costs.

Study description

Background summary

Pancreatic necrosis is a severe complication of acute pancreatitis. Infected necrosis is generally accepted as an indication for surgery. Majority of patients with sterile necrosis can be successfully treated without intervention. However a subgroup of patients with sterile necrosis suffers from persisting symptoms of residual pain, difficulty eating, jaundice, malaise, subfebrile temperature and general lack of wellbeing resulting in high health care utilization and preventing return to work for many months. Surgical management is however associated with significant morbidity and mortality. By the time necrosis becomes organized, endoscopic therapy has the potential to offer an alternative treatment. Recently we have performed a retrospective study of all patients treated with transmural endoscopic debridement with compelling results. Because of the minimal invasiveness, compelling initial

results and relative safeness, endoscopic debridement could be of benefit in patients with sterile pancreatic necrosis who suffer from longstanding *failure to thrive* after the acute fase of necrotizing pancreatitis.

Study objective

To compare endoscopic transmural debridement with standard conservative treatment in patients with symptomatic sterile organized pancreatic necrosis in a randomized controlled trial with emphasis on extent and duration of recovery.

Study design

A multicenter randomised controlled, clinical trial.

Intervention

Patients will be randomly assigned to receive either endoscopic transmural debridement or standard conservative treatment.

Study burden and risks

Main burden are the extra endoscopic procedures which need to be performed. Consequently there will be a small risk of bleeding or perforation. In the participating centers there will be adequate experience with this interventional technique.
The patients treated conservatively will be at risk of complications of the remaining necrosis, for expamle infection. There also will be a chance that symptoms will persist and patients still need to underwent an endoscopic intervenion.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

*Presence of a single (>6cm), large, well defined (peri)pancreatic fluid collection on contrast-enhanced computed tomography (CECT) or a similar fluid collection on MRI also containing necrotic material larger than 1 cm in diameter.
*The presence of at least one of the following persistent symptoms, suspected to be caused by the fluid collection, despite of conservative treatment of minimally 6 weeks after onset of acute necrotizing pancreatitis: Severe abdominal pain, Gastric outlet obstruction or obstructive jaundice
* Window for transluminal endoscopic debridement
* Age equal to or above 18 years
* Written informed consent

Exclusion criteria

* Infected pancreatic necrosis, defined as the presence of air in the collection on CECT.
* Suspected infected necrosis, defined as a rise of two out of three following parameters: >50% increase of leucocytes or CRP or temperature rises above 38,5oC within 72 hours.
* New failure of at least one of the following organs: cardiac, pulmonary or renal.
* Acute flare-up of chronic pancreatitis
* Previous endoscopic (transgastric or transduodenal), percutaneous or surgical drainage of a pancreatic fluid collection

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2007
Enrollment:	58
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL20219.018.07