# Standard CONservative approach versus endoscopic Debridement in patients with symptomatic sterile Organized pancReatic necrosis (CONDOR trial): a prospective randomised controlled trial.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON22846

**Source**
Nationaal Trial Register

**Brief title**
CONDOR

**Health condition**

Acute necrotizing pancreatitis.

### Sponsors and support

**Primary sponsor:** Academic Medical Center (AMC), Department of Gastroenterology
**Source(s) of monetary or material Support:** Academic Medical Center (AMC), Department of Gastroenterology

### Intervention

## 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 and (in)direct costs.

# Study description

### Background summary

A randomized trial comparing standard conservative approach versus endoscopic debridement in patients with symptomatic sterile organized pancreatic necrosis with emphasis on extent and duration of recovery.

### Study objective

Primairy aim is 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

N/A

### Intervention

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

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. 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;

2. 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:

a. Severe abdominal pain, defined as abdominal pain insufficiently relieved by non-narcotic analgesic (paracetamol (max 4000 mg/ day) and NSAIDS (equivalent to diclofenac (max 150 mg/day)) or requiring opiates;

b. Gastric outlet obstruction, defined as inability to tolerate oral solid intake or the need for gastro-jejeunal tube feeding;

c. Obstructive jaundice, dark urine, pale stools and serum total bilirubine values increased above 50 ìmol/l;

3. Fluid collection is in the immediate proximity of stomach and/or duodenum and seems to be accessible to endoscopic drainage based on the CT- or MRI-information;

4. Age equal to or above 18 years;

5. Written informed consent.

### Exclusion criteria

1. Infected pancreatic necrosis, defined as the presence of air in the collection on CECT;

2. Suspected infected necrosis, defined as a rise of two out of three following parameters:>50% increase of leucocytes (minimal >15 10E9/L) or CRP (minimal >50 mg/L) or temperature rises above 38,5oC within 72 hours (with exclusion of other infectious causes);

3. New failure of at least one of the following organs: cardiac, pulmonary or renal;

4. Acute flare-up of chronic pancreatitis;

5. Previous endoscopic (transgastric or transduodenal), percutaneous or surgical drainage of a pancreatic fluid collection;

6. Unable to undergo upper gastrointestinal endoscopy.

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Placebo |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 02-02-2008 |
| Enrollment: | 58 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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|---|---|
| Date: | 16-01-2008 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL1145 |
| NTR-old | NTR1187 |
| Other | : MEC 07/281 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Study results

**Summary results**
N/A