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

Gepubliceerd: 16-01-2008 Laatst bijgewerkt: 18-08-2022

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.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON22846

**Bron**
Nationaal Trial Register

**Verkorte titel**
CONDOR

**Aandoening**

Acute necrotizing pancreatitis.

### Ondersteuning

**Primaire sponsor:** Academic Medical Center (AMC), Department of Gastroenterology
**Overige ondersteuning:** Academic Medical Center (AMC), Department of Gastroenterology

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Extent and duration of recovery measured by the Sickness Impact Profile (SIP) after 12 weeks.

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

### Onderzoeksopzet

N/A

### Onderzoeksproduct en/of interventie

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

# Contactpersonen

## Publiek

Academic Medical Center (AMC) <br>Department of Gastroenterology <br>
P.O. Box 22660
P. Fockens
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands

+31 (0)20 5669111

### Wetenschappelijk

Academic Medical Center (AMC) <br>Department of Gastroenterology <br>
P.O. Box 22660
P. Fockens
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5669111

## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Enkelblind |
| Controle: | Placebo |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 02-02-2008 |
| Aantal proefpersonen: | 58 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 16-01-2008 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL1145 |
| NTR-old | NTR1187 |
| Ander register | : MEC 07/281 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Resultaten

**Samenvatting resultaten**
N/A