# Pancreatitis, ENdoscopic transGastric versUs primary necrosectomy in patients with Infected Necrosis

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
11/12/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/03/2007	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
21/03/2012	Digestive System	

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

Protocol serial number N/A

# Study information

Scientific Title

Pancreatitis, ENdoscopic transGastric versUs primary necrosectomy in patients with Infected Necrosis: a randomised controlled multicentre observer-blinded trial (Dutch Acute Pancreatitis Study Group)

#### Acronym

**PENGUIN** 

#### **Study objectives**

Endoscopic transgastric necrosectomy will lead to a reduction of the pre- and post-operative proinflammatory response, as compared to necrosectomy by laparotomy, in patients with infected (peri-)pancreatic necrosis.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Regional Medical Ethics Board for the Meander Medical Centre Amersfoort-Baarn-Soest (De Verenigde Commissies Mensgebonden Onderzoek [VCMO]) approved on the 17th April 2007 (ref: LTME/VL-07.08)

#### Study design

Randomised controlled multicentre observer-blinded trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Acute necrotising pancreatitis

#### **Interventions**

Endoscopic transgastric necrosectomy or necrosectomy by laparotomy, followed by continuous post-operative lavage

## Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome(s)

Pro-inflammatory response as measured by the maximum increase in level of serum cytokine Interleukin six (IL-6) in the period between start of the first necrosectomy and five hours thereafter

# Key secondary outcome(s))

1. Complications (bleeding, perforation, pancreatic fistula, pancreatic pseudocyst requiring intervention, pancreatic abscess requiring intervention, biliary strictures, incisional hernia

requiring re-intervention and pancreatic insufficiency)

- 2. Mortality
- 3. Total number of interventions
- 4. Total hospital stay
- 5. Total intensive care stay

#### Completion date

01/03/2009

# Eligibility

#### Key inclusion criteria

- 1. Age equal to or above 18 years
- 2. Pancreatic necrosis or peripancreatic necrosis detected on contrast-enhanced computed tomography (CECT)
- 3. Patients in whom a decision for surgical intervention has been made because of (suspected) infected (peri-)pancreatic necrosis
- 4. Safe access route for endoscopic transgastric necrosectomy
- 5. Written informed consent

#### Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

# Lower age limit

18 years

#### Sex

**Not Specified** 

#### Key exclusion criteria

- 1. Participation in another intervention trial that would interfere with the intervention and outcome of this study
- 2. Previous surgical necrosectomy for (suspected) infected pancreatic necrosis, including procedures performed in referring hospitals. Previous percutaneous or transgastric drainage is allowed
- 3. Previous exploratory laparotomy for acute abdomen and diagnosis of pancreatitis during laparotomy
- 4. Acute flare-up of chronic pancreatitis
- 5. Bleeding, abdominal compartment syndrome or perforation of a visceral organ as indication for intervention
- 6. Post-abdominal surgery necrotising pancreatitis

#### Date of first enrolment

01/03/2007

# Date of final enrolment

01/03/2009

# Locations

#### Countries of recruitment

Netherlands

Study participating centre St Antonius Hospital Nieuwegein Netherlands 3402 EM

# Sponsor information

#### Organisation

St Antonius Hospital Nieuwegein (Netherlands)

#### **ROR**

https://ror.org/01jvpb595

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

University Medical Centre Utrecht (UMCU) (Netherlands)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Results article results 14/03/2012 Yes

No