

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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 pro-inflammatory 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)

Primary study design

Interventional

Study design

Randomised controlled multicentre observer-blinded trial

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				

[Results article](#)

14/03/2012

Yes

No