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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 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)

Study design
Randomised controlled multicentre observer-blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/03/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
20

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)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website

http://www.antonius.net/rood/english.php

ROR
https://ror.org/01jvpb595

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Utrecht (UMCU) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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