ISRCTN13975868 https://doi.org/10.1186/ISRCTN13975868

Minimally invasive step up approach versus maximal necrosectomy in patients with acute necrotising pancreatitis

Submission date 22/04/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/04/2005	**Overall study status** Completed	
Last Edited 27/04/2010	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.pancreatitis.nl/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
04-289

Study information

Scientific Title
Minimally invasive step up approach versus maximal necrosectomy in patients with acute necrotising pancreatitis: a randomised controlled trial by the Dutch Acute Pancreatitis Study Group

Acronym
PANTER

Study objectives
Minimally invasive step up approach, as compared to laparotomy, is capable of reducing major morbidity in patients with infected necrotising pancreatitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study is conducted in accordance with the principles of the Declaration of Helsinki and 'good clinical practice' guidelines. The independent medical ethics committees of all 20 participating hospitals have approved the study protocol. Prior to randomisation, written informed consent will be obtained from all patients (alternatively consent by proxy will be obtained for patients who are unable to give consent, e.g., intubated patients).

Study design
Randomised controlled 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
Infected necrotising pancreatitis

Interventions

Minimally invasive step up approach: percutaneous catheter drainage, when necessary followed by minimally invasive surgical necrosectomy versus laparotomy and continuous postoperative lavage.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Complications and mortality, expressed as the percentage of patients who died or had one or more of the complications listed in the protocol. Each complication will be assessed separately.

Secondary outcome measures
1. Hospital and intensive care stay
2. Total indirect and direct costs
3. Hospital stay after first intervention
4. Duration of intubation after first intervention
5. Quality of life

Overall study start date
01/05/2005

Completion date
31/05/2008

Eligibility

Key inclusion criteria
Patients of all Dutch University Medical Centers and 12 teaching hospitals who are diagnosed with (suspected) infected necrotising pancreatitis:
1. Aged equal to or above 18 years
2. Pancreatic necrosis or peripancreatic necrosis detected on CECT
3. Patients in whom a decision for surgical intervention has been made because of (suspected) infected (peri-)pancreatic necrosis
4. Possibility of placing a drain (either percutaneous or endoscopic) in the collection(s)
5. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
94

Key exclusion criteria
1. Previous percutaneous drainage, endoscopic drainage or surgical necrosectomy for necrotising pancreatitis (endoscopic retrograde cholangio-pancreatography [ERCP] for biliary pancreatitis is allowed)
2. Acute attack in a patient with chronic pancreatitis
3. Participation in another intervention trial that would interfere with the intervention and outcome of this study
4. Acute primary intervention because of acute abdomen, bleeding or perforation of a visceral organ
5. Post-operative (i.e. abdominal surgery) necrotising pancreatitis

Date of first enrolment
01/05/2005

Date of final enrolment
31/05/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Heidelberglaan 100
Utrecht
Netherlands
3584CX

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (Netherlands)

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Sponsor type
University/education

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands) (ref: 945-06-910)

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?
Protocol article	protocol	11/04/2006		Yes	No
Results article	results	22/04/2010		Yes	No