

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

Submission date 22/04/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 26/04/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/04/2010	Condition category Digestive System	<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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	22/04/2010		Yes	No
Protocol article	protocol	11/04/2006		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes