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Postponed or immediate drainage of infected necrotizing pancreatitis (POINTER trial)

Submission date
02/07/2015

Recruitment status
No longer recruiting

Registration date
06/08/2015

Overall study status
Completed

Last Edited
17/07/2023

Condition category
Digestive System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Acute pancreatitis is a common disease where the pancreas becomes inflamed over a short period of time. During an acute pancreatitis attack, tissue within the pancreas may die (necrotize) and later become infected. Infected necrosis is associated with a mortality (death rate) of 20% and many other complications. Current guidelines recommend a so-called 'step-up approach' in these patients, starting with first catheter drainage. If necessary, patients will have an additional operation to remove their infected necrosis (necrosectomy). All these interventions are preferably delayed until the necrotic collections have reached the stage of walled-off necrosis. This process usually takes 4 weeks. During this waiting period antibiotic treatment is used. There is evidence that necrosectomy (second step) should be postponed until walled-off necrosis. However, evidence regarding the best timing of catheter drainage (first step) is lacking. This study aims to compare immediate and postponed catheter drainage in patients with infected necrotizing pancreatitis with regard to clinical outcomes and medical costs.

Who can participate?
Adult patients with (suspected) infected necrotizing pancreatitis.

What does the study involve?
Participants will be randomly allocated to either the intervention or the control group. Participants will undergo the same treatment as non-participating patients. The only difference is that participants in the intervention group will undergo catheter drainage earlier in the disease course. Participants will attend follow-up visits 3 and 6 months later to undergo routine tests (e.g., pancreatic function tests and imaging).

What are the possible benefits and risks of participating?
There is a rationale in postponing catheter drainage in patients with infected necrotizing pancreatitis. First, antibiotic treatment alone may suffice as treatment. Second, diagnosing infected necrotizing pancreatitis is often easier in a later stage of the disease. Third, catheter drainage may be easier once the stage of walled-off necrosis has been reached. On the other hand there is not always a technical reason to wait several weeks until full encapsulation of the collections and catheter drainage can be performed successfully in the first weeks after onset of

disease. For similar abdominal conditions catheter drainage is also safely performed early in ‘non-walled-off’ collections. If there is no technical reason for postponing catheter drainage, patients with infected necrotizing pancreatitis may benefit from earlier catheter drainage by reduced complications and length of hospital stay.

Where is the study run from?
The study is initiated by the Dutch Pancreatitis Study Group (DPSG) and 24 Dutch hospitals will participate.

When is the study starting and how long is it expected to run for?
The study will start in July 2015 and will run for 3 years. Thereafter the follow-up will be completed in 6 months, followed by 6 months for data collecting, analysing and reporting. The total duration of the study is 4 years.

Who is funding the study?
Fonds NutsOhra and the Amsterdam UMC, location Academic Medical Center Amsterdam.

Who is the main contact?
1. Dr Lotte Boxhoorn
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2. Dr Marc Besselink
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Study website
http://www.pancreatitis.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
N/A

Study information

Scientific Title
Postponed or immediate drainage of infected necrotizing pancreatitis: a pragmatic parallel group randomized controlled multicenter superiority trial

Acronym
POINTER trial

Study objectives
Immediate catheter drainage is clinically and economically superior to postponed catheter drainage within the step-up approach in infected necrotizing pancreatitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The medical ethics committee of the Amsterdam UMC, location Academic Medical Center Amsterdam, 19/06/2015, NL52361.018.15

Study design
Pragmatic parallel-group randomized controlled multicenter superiority trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Infected necrotizing pancreatitis

Interventions
Immediate catheter drainage after diagnosing infected necrosis while starting antibiotic treatment versus current standard treatment with postponing catheter drainage under antibiotic treatment (preferably until walled-off necrosis). If necessary a necrosectomy will be performed and postponed, if feasible, until the stage of walled-off necrosis in both treatment arms.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measure as of 12/04/2021:
Comprehensive Complication Index (CCI), including all complications other than pre-existent complications (e.g. treatment for infected (extra) pancreatic necrosis) occurring after randomization until 6 months after randomization, and graded according to the Clavien-Dindo classification.

Previous primary outcome measure:
The Comprehensive Complication Index (CCI), including all complications between randomization and 6 months after

Secondary outcome measures
Current secondary outcome measures as of 12/04/2021:
1. Mortality
2. New onset (multi-)organ failure
3. Bleeding requiring intervention
4. Perforation of a visceral organ requiring intervention
5. Enterocutaneous fistula
6. Pancreaticocutaneous fistula
7. Incisional hernia
8. Wound infections
9. Endocrine and exocrine pancreas insufficiency
10. Number of patients with severe complications (Clavien-Dindo III or higher)
11. Number of patients per Clavien-Dindo classification
12. Number of surgical, endoscopic and radiologic interventions
13. Length of hospital stay
14. Length of ICU admission
15. QALYs

16. Total direct and indirect costs
17. Budget impact
All secondary endpoints occurring within 6 months after randomization will be measured

Previous secondary outcome measures:
1. Mortality
2. New onset (multi-)organ failure
3. Bleeding requiring intervention
4. Perforation requiring intervention
5. Fistula
6. Incisional hernia
7. Wound infections
8. Endocrine and exocrine pancreas insufficiency
9. Number of patients with severe complications (Clavien-Dindo III or higher)
10. Number of patients per Clavien-Dindo classification
11. Number of (re-)interventions
12. Hospital and ICU length of stay
13. QALYs
14. (In)direct costs
15. Budget impact
All secondary endpoints occurring within 6 months after randomization will be measured.

Overall study start date
01/07/2015

Completion date
11/04/2019

Eligibility

Key inclusion criteria
Adult patients with (suspected) infected necrotizing pancreatitis; all patients with necrotizing pancreatitis will be screened for eligibility including a protocolized approach to patients with signs of infection

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
104

Total final enrolment
104

Key exclusion criteria
1. More than 35 days after onset of acute pancreatitis
2. Indication for emergency laparotomy for abdominal catastrophe (e.g. bleeding, bowel perforation, abdominal compartment syndrome)
3. Previous retroperitoneal intervention for necrotizing pancreatitis
4. Documented chronic pancreatitis

Date of first enrolment
04/08/2015

Date of final enrolment
11/10/2019

Locations

Countries of recruitment
Netherlands

Study participating centre
Amsterdam UMC, location Academic Medical Center
Amsterdam
Netherlands
-

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
-

Study participating centre
St. Antonius Hospital
Nieuwegein
Netherlands
-

Study participating centre
Maastricht University Medical Center
Maastricht
Netherlands
-

Study participating centre
Radboudumc
Nijmegen
Netherlands
-

Study participating centre
University Medical Center Groningen
Groningen
Netherlands
-

Study participating centre
University Medical Center Utrecht
Utrecht
Netherlands
-

Study participating centre
Jeroen Bosch Hospital
’s-Hertogenbosch
Netherlands
-

Study participating centre
Reinier de Graaf Gasthuis
Delft
Netherlands
-

Study participating centre
Amsterdam UMC, location VU University Medical Center
Amsterdam
Netherlands
-

Study participating centre

Meander Medical Center
Amersfoort
Netherlands
-

Study participating centre
Hospital Gelderse Vallei
Ede
Netherlands
-

Study participating centre
Maxima Medisch Centrum
Veldhoven
Netherlands
-

Study participating centre
Isala Klinieken
Zwolle
Netherlands
-

Study participating centre
Rijnstate Hospital
Arnhem
Netherlands
-

Study participating centre
Medisch Spectrum Twente
Enschede
Netherlands
-

Study participating centre

Catharina Hospital
Eindhoven
Netherlands
-

Study participating centre
Gelre Hospital
Apeldoorn
Netherlands
-

Study participating centre
Medical Center Leeuwarden
Leeuwarden
Netherlands
-

Study participating centre
Onze Lieve Vrouwe Gasthuis
Amsterdam
Netherlands
-

Study participating centre
Amphia Hospital
Breda
Netherlands
-

Study participating centre
Maasstad Hospital
Rotterdam
Netherlands
-

Study participating centre

Spaarne Gasthuis
Haarlem
Netherlands
-

Study participating centre
Albert Schweitzer Hospital
Dordrecht
Netherlands
-

Sponsor information

Organisation
Academic Medical Center

Sponsor details
Meibergdreef 9
Amsterdam
Netherlands
PO Box 22660 / 1100 DD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Charity

Funder Name
Fonds NutsOhra

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan, as of 12/04/2021:
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/10/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. dr. Marc Besselink (m.g.besselink@amsterdamumc.nl)

Previous publication and dissemination plan:
To be confirmed on a later date

IPD sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Marc Besselink (m.g.besselink@amc.uva.nl)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/04/2019	29/04/2019	Yes	No
Results article		07/10/2021	07/10/2021	Yes	No
Results article		17/07/2023	17/07/2023	Yes	No