

Transluminal endoscopic step-up approach versus minimally invasive surgical step-up approach in patients with infected pancreatic necrosis

Submission date 27/07/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/09/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/11/2017	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.pancreatitis.nl>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Transluminal endoscopic step-up approach versus minimally invasive surgical step-up approach in patients with infected pancreatic necrosis: TENSION, a randomised controlled parallel-group superiority multicentre trial (Dutch Pancreatitis Study Group)

Acronym

TENSION

Study objectives

Endoscopic transluminal 'step-up' approach, compared to the surgical 'step-up' approach, reduces mortality and/or major morbidity in patients with (suspected or confirmed) infected necrotising pancreatitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Ethics Committee (MEC), Academic Medical Center, Amsterdam, 31/01/2011, ref: MEC 10 /203

Study design

Randomised controlled parallel group superiority multicentre 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 contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Infected necrotising pancreatitis

Interventions

1. Intervention group: endoscopic transluminal step-up approach, consisting of endoscopic transluminal catheter drainage (ETD) and endoscopic transluminal necrosectomy (ETN)
2. Control group: surgical step-up approach, consisting of percutaneous catheter drainage (PCD) and video assisted retroperitoneal debridement (VARD), if not possible laparotomy

The total duration of follow-up is 6 months after discharge. There is no total duration of treatment because patients will be randomized at different moments. This depends on the fact when infected necrotizing pancreatitis is suspected or confirmed. This can be 30 days after admission but also 90 days after admission.

Intervention Type

Procedure/Surgery

Primary outcome measure

Composite of mortality and major morbidity. Major morbidity is defined as new onset organ failure (cardiac, pulmonary or renal), bleeding requiring intervention, perforation of a visceral organ (except for the stomach in ETN) requiring intervention, enterocutaneous fistula requiring intervention and incisional hernia (including burst abdomen). Measured at 6 months.

Secondary outcome measures

Measured at 6 months:

1. Individual components of primary composite endpoint
2. Other morbidity such as pancreaticocutaneous fistula
3. Exocrine and/or endocrine pancreatic insufficiency
4. Development of additional fluid collections requiring intervention
5. Biliary strictures
6. Wound infections
7. The need for necrosectomy (either endoscopically or surgically)
8. The total number of surgical, endoscopic or radiological (re-) interventions
9. Total length of intensive care and hospital stay
10. Quality of life
11. Costs per patient with poor outcome
12. Costs per quality adjusted life year (QALY)
13. Total direct and indirect medical costs
14. Total number of cross-overs between groups

Overall study start date

01/03/2011

Completion date

31/12/2013

Eligibility

Key inclusion criteria

1. Pancreatic necrosis and/or peripancreatic necrosis with (suspected or confirmed) infection
2. The peripancreatic collection is amenable to the endoscopic transluminal 'step-up' approach as well as the surgical 'step-up' approach
3. Aged greater than or equal to 18 years (either sex) and informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

98

Key exclusion criteria

1. Previous surgical, endoscopic or percutaneous intervention for pancreatic necrosis and/or peripancreatic necrosis and/or peripancreatic collections
2. Acute flare up of chronic pancreatitis
3. Concomitant indication for laparotomy because of suspected abdominal compartment syndrome, bleeding or perforation of a visceral organ

Date of first enrolment

01/03/2011

Date of final enrolment

31/12/2013

Locations**Countries of recruitment**

Netherlands

Study participating centre

Academic Medical Center

Amsterdam

Netherlands

1100DD

Sponsor information**Organisation**

Academic Medical Centre (AMC) (Netherlands)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.pancreatitis.nl>

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Research organisation

Funder Name

Maag Lever Darm Stichting (MLDS) (Netherlands) - partial funding (ref: JB/2009-049)

Funder Name

Fonds NutsOhra (The Netherlands) - partial funding

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	06/01/2018		Yes	No