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

Submission date
27/07/2010

Registration date
06/09/2010

Last Edited
08/11/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes