ISRCTN09186711 https://doi.org/10.1186/ISRCTN09186711

# 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

**Registration date**
06/09/2010

**Overall study status**
Completed

**Last Edited**
08/11/2017

**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

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

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof P Fockens

**Contact details**
Dutch Pancreatitis Study Group
Department of Gastroenterology
Academic Medical Center
PO Box 22660
Amsterdam
Netherlands
1100DD
+31 (0)20 566 3632
p.fockens@amc.uva.nl

## 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**

Dutch Pancreatitis Study Group
Department of Gastroenterology
PO Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)61 903 0931
p.fockens@amc.uva.nl

### 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 |