

Transluminal Endoscopic step-up approach versus miNimally invasive Surglcal step-up apprOach in patients with infected pancreatic Necrosis: TENSION, a randomized controlled parallel-group superiority multicenter trial. Dutch Pancreatitis Study Group.

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To determine the effectiveness and, subsequently, the cost-effectiveness of a endoscopic transluminal step-up approach (ETD & ETN) versus a surgical step-up approach (PCD & VARD ,if not possible laparotomy) to improve clinical outcome in...

Ethical review	-
Status	Recruitment stopped
Health condition type	Gastrointestinal infections
Study type	Interventional

Summary

ID

NL-OMON38023

Source

ToetsingOnline

Brief title

TENSION

Condition

- Gastrointestinal infections
- Bacterial infectious disorders
- Gastrointestinal therapeutic procedures

Synonym

infected necrotizing pancreatitis, Pancreatitis

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: infection, intervention, necrosis, pancreatitis

Outcome measures**Primary outcome**

The primary endpoint is 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).

Secondary outcome

Secondary endpoints are the individual components of the primary endpoint, other morbidity such as pancreaticocutaneous fistula, exocrine and/or endocrine pancreatic insufficiency, development of additional fluid collections requiring intervention, biliary strictures, wound infections, the need for necrosectomy (either endoscopically or surgically), the total number of surgical, endoscopic or radiological (re-) interventions, total length of intensive care- and hospital stay, quality of life, costs per patient with poor outcome, costs per QALY, total direct and indirect medical costs and the total number of

cross-over between groups.

Other research questions:

Is endoscopic transluminal catheter drainage (ETD) equally effective as percutaneous catheter drainage (PCD) in preventing necrosectomy?

Study description

Background summary

Infected necrotising pancreatitis is a dangerous, potentially lethal disease, that requires intervention. It is associated with prolonged hospital stay and high costs. It has been shown that catheter drainage is the optimal first step in the treatment of infected necrosis. Recent literature suggests that the endoscopic transluminal step-up approach (endoscopic transluminal catheter drainage (ETD) and necrosectomy (ETN) as the second step), may further improve outcome (risk of mortality and major morbidity) compared to the surgical step-up approach (consisting of percutaneous catheter drainage (PCD) and surgical necrosectomy (VARD, if not possible laparotomy) as the second step).

Study objective

To determine the effectiveness and, subsequently, the cost-effectiveness of a endoscopic transluminal step-up approach (ETD & ETN) versus a surgical step-up approach (PCD & VARD ,if not possible laparotomy) to improve clinical outcome in patients with (suspected or confirmed) infected necrotizing pancreatitis.

Study design

Randomized controlled, parallel group superiority multicenter trial with a follow-up of 6 months after randomisation for the primary endpoint, secondary endpoint and the other research questions.

Intervention

Endoscopic transluminal step-up approach (ETD and ETN).

Study burden and risks

In the endoscopic transluminal step-up approach group, the patient will initially be drained endoscopically transluminally. If the patient does not show clinical improvement within 72 hours, endoscopic transluminal necrosectomy will take place. The study entails little additional risks. The endoscopic transluminal step-up approach is already enrolled in many centers around the world and published literature shows that it is a safe technique that, compared to the surgical step-up approach is associated with few complications. Both approaches are applied only by experienced specialists in experienced centers.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

* Pancreatic necrosis and/or peripancreatic necrosis with (suspected or confirmed) infection.
(See protocol, page 15-16 for definitions)

- * The peripancreatic collection is amenable to the endoscopic transluminal step-up approach as well as the surgical step-up approach.
- * Age * 18 years and informed consent.

Exclusion criteria

- * Previous surgical, endoscopic or percutaneous intervention for pancreatic necrosis and/or peripancreatic necrosis and/or peripancreatic collections. (See protocol, page 16 for definition)
- * Acute flare up of chronic pancreatitis.
- * Concomitant indication for laparotomy because of suspected abdominal compartment syndrome, bleeding or perforation of a visceral organ.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2011
Enrollment:	98
Type:	Actual

Ethics review

Approved WMO	
Date:	10-08-2012

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	15-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	23-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	08-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL33422.018.10