

Transluminal Endoscopic step-up approach versus miNimally invasive Surglcal step-up apprOach in patients with infected pancreatic Necrosis (TENSION). Long-term outcomes of a step-up endoscopic versus surgical step-up approach

Published: 09-03-2020

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Primary Objective: In accordance with the original study, 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,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal infections
Study type	Observational invasive

Summary

ID

NL-OMON49170

Source

ToetsingOnline

Brief title

Long-term outcomes TENSION trial

Condition

- Gastrointestinal infections

Synonym

infected necrotizing pancreatitis, pancreatitis

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: Infection, Necrosis, Pancreatitis, TENSION

Outcome measures

Primary outcome

In accordance with the original study, 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 requiring intervention, enterocutaneous fistula requiring intervention and incisional hernia.

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.

Study description

Background summary

Acute pancreatitis is the most common gastrointestinal diagnosis requiring hospital admission. Most patients experience a mild clinical course and can be managed with fluid resuscitation and pain control. Approximately 20% of patients develop a severe pancreatitis with necrosis of the (peri)pancreatic tissue. According to the evidence based international guidelines, suspected or proven infected necrosis is an indication for invasive intervention in patients who clinically deteriorate.

During the last decades, the management of infected necrotizing pancreatitis developed from open necrosectomy to a minimally invasive step-up approach. The TENSION trial compared endoscopic step-up approach to surgical step-up approach in these patients and showed that there was no difference in mortality and major morbidity between the endoscopic and minimally invasive surgical approach. However, the endoscopic approach resulted in a shorter hospital stay and reduced costs.

These results resulted in a shift to the endoscopic step-up approach as the preferred treatment strategy. It is however unclear whether these patients underwent additional interventions in the period beyond the original follow-up period (i.e. the first 6 months after discharge). Moreover, the incidence of long-term complications such as pancreatic exocrine and endocrine insufficiency and impact of quality of life on patients with necrotizing pancreatitis may differ between the endoscopically and surgically treated patients.

Study objective

Primary Objective:

In accordance with the original study, 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 requiring intervention, enterocutaneous fistula requiring intervention and incisional hernia.

Secondary Objective(s):

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.

Study design

Observational long term follow-up cohort study of patients with (suspected or confirmed) infected necrotizing pancreatitis who were randomized in the TENSION trial and were therefore received the endoscopic or surgical step-up approach.

Study burden and risks

The risk for the patient is vanishingly small

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

Patients included in the TENSION trial

Exclusion criteria

No permission for follow up after the TENSION trial

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 08-04-2020

Enrollment: 98

Type: Actual

Ethics review

Approved WMO

Date: 09-03-2020

Application type: First submission

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	NL72370.018.20