PENGUIN-trial: pancreatitis, endoscopic transgastric versus primary necrosectomy in patients with infected necrosis. A randomised controlled multicenter observer-blinded trial

Published: 12-04-2007
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To investigate if endoscopic transgastric necrosectomy will lead to a reduction ofthe per- and postoperative pro-inflammatory response, as compared to necrosectomy by laparotomy, in patients with infected (peri-)pancreatic necrosis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON33864

Source
ToetsingOnline

Brief title
PENGUIN-trial

Condition

- Gastrointestinal inflammatory conditions

Synonym
Infection of pancreas, pancreatitis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: endoscopic transgastric, necrosectomy, necrotizing, pancreatitis

Outcome measures

Primary outcome

The primary endpoint is the total pro-inflammatory response as measured by the maximum increase in level of serum cytokine IL-6 in the period between start of the first necrosectomy and five hours thereafter.

Secondary outcome

Secondary endpoints are complications (bleeding, perforation, pancreatic fistula, pancreatic pseudocyst requiring intervention, pancreatic abscess requiring intervention, biliary strictures, incisional hernia requiring re-intervention and pancreatic insufficiency) and mortality, total number of interventions, hospital and intensive care stay.

Study description

Background summary

Infected necrotizing pancreatitis is an indication for surgical necrosectomy by laparotomy. Mortality in these patients is caused by septic multi-organ failure. It has been hypothesized that minimally invasive transgastric

endoscopic necrosectomy might reduce the per- and postoperative inflammatory response and thereby reduce morbidity and mortality.

Study objective

To investigate if endoscopic transgastric necrosectomy will lead to a reduction of
the per- and postoperative pro-inflammatory response, as compared to necrosectomy by laparotomy, in patients with infected (peri-)pancreatic necrosis.

Study design

A randomised controlled parallel group superiority multicenter observerblinded trial.

Intervention

Patients will be randomly assigned to receive either
endoscopic transgastric necrosectomy or necrosectomy by laparotomy and continuous postoperative lavage.

Study burden and risks

Blood samples will be drawn from a permanent peripheral venous line at time 0 (before first intervention), after 2 hours, 5 hours, 24 hours and 7 days after start of necrosectomy. In the participating centres there is adequate experience with both interventional techniques. There is are no extra burden or risk associated with participation in this study. If endoscopic transgastric necrosectomy is associated with a lower inflammatory response; this might be beneficial in terms of morbidity and mortality.

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

- Age equal to or above 18 years
- Pancreatic necrosis or peripancreatic necrosis detected on CECT.
- Patients in whom a decision for surgical intervention has been made because of (suspected) infected (peri-)pancreatic necrosis
- Safe access route for endoscopic transgastric necrosectomy
- Written informed consent

Exclusion criteria

- Participation in another intervention trial that would interfere with the intervention and outcome of this study
- Previous surgical necrosectomy for (suspected) infected pancreatic necrosis, Including procedures performed in referring hospitals. Previous percutaneous or transgastric drainage is allowed.
- Previous exploratory laparotomy for acute abdomen and diagnosis of pancreatitis during laparotomy
- Acute flare-up of chronic pancreatitis
- Bleeding, abdominal compartment syndrome or perforation of a visceral organ as indication for intervention
- Post-abdominal surgery necrotizing pancreatitis

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-08-2008
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	12-04-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-04-2009
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-04-2009
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	09-12-2009
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL15399.100.06
Other	volgt