AXIOMA: Hot AXIOS metal stent for infected walled-off pancreatic necrosis management.

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Investigate whether the use of the Hot AXIOS lumen apposing metal stent is superior to standard plastic pigtails stents for drainage of infected pancreatic necrosis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50645

Source
ToetsingOnline

Brief title
AXIOMA

Condition

- Other condition
- Exocrine pancreas conditions
- Gastrointestinal therapeutic procedures

Synonym
Infected necrotizing pancreatitis

Health condition

Endoscopische verrichtingen

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Boston Scientific Cooperation International,Gehonoreerde subsidie aanvraag bij Industrie (Boston Scientific).

Intervention

Keyword: Hot AXIOS stent, Infection, Necrosis, Pancreatitis

Outcome measures

Primary outcome

Primary endpoint is the need for additional (endoscopic) necrosectomy to

achieve clinical success.

Secondary outcome

- Endoscopic morbidity (bleeding, perforation, stent migration or stent

dysfunction)

- Mortality

- Pancreaticocutaneous fistula

- Biliary stricture, requiring ERPC or PTC

- New onset organ failure (cardiovascular, pulmonary, renal)

- Additional radiological, endoscopic or surgical interventions

- Number of endoscopic, radiological or surgical intervention

- Total length of hospital stay

- Exocrine and/or endocrine pancreatic insufficiency

- Total length of Intensive care stay

- Disease related death

- Overall survival

- Medical costs

Study description

Background summary

Infected necrotizing pancreatitis complicates 10% of all acute pancreatitis episodes and is associated with a 20% mortality. Currently, the *step-up approach* is the treatment of choice, consisting of catheter drainage and, if necessary, followed by a minimally invasive necrosectomy.This can either be performed via a percutaneous or endoscopic approach. The latter is less invasive and associated with less pancreatic fistula and shorter hospital stay. An increasing number of studies suggest that optimal drainage is the cornerstone of the treatment of infected pancreatic necrosis. By optimizing endoscopic transluminal drainage necrosectomy can be prevented or limited. The use of the Hot AXIOS-stent might optimize endoscopic drainage and therefore reduce the need for additional endoscopic necrosectomy and its associated morbidity and costs.

Study objective

Investigate whether the use of the Hot AXIOS lumen apposing metal stent is superior to standard plastic pigtails stents for drainage of infected pancreatic necrosis.

Study design

Prospective multicenter study in centers of the nationwide Dutch Pancreatitis Study Group. Patients who fulfill the inclusion criteria and give written informed consent for participating in the study receive the investigational treatment of endoscopic transluminal drainage with the Hot AXIOS metal stent. This cohort of patients will be compared with the 58 endoscopically treated patients of the TENSION and the PENGUIN trial. These patients received endoscopic transluminal drainage with plastic pigtails stents.

Intervention

Endoscopic transluminale drainage with the Hot AXIOS stent.

Study burden and risks

By optimizing endoscopic transluminal drainage, the need for additional endoscopic necrosectomy might be prevented or limited. Optimal endoscopic

drainage might prevent further deterioration of these patients and therefore leads to less complications, lowers hospital stay and medical costs. The Hot AXIOS stent was developed within the same framework of previous stents with the aim of gaining improvement in patient outcomes. Therefore, the stent might present an incremental innovation with respect to previous stents. Literature reports that the use to of LAMS is safe and effective. However, some adverse events, for instance major bleeding, have been described as well. Recent literature shows that the use of metal stents is associated with lower bleeding, a trend toward lower perforation and stent occlusion, although with higher migration, which may result in an additional procedure to replace the stent.

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

- * 18 years old
- Written informed consent
- Walled-off pancreatic necrosis
- Suspected or documented infected walled-off pancreatic necrosis
- Endoscopic transluminal drainage is technically feasible as deemed by the Expert panel and/or treating physician.

Exclusion criteria

- Previous invasive intervention for (peri)pancreatic necrosis and/or peripancreatic collections
- Indication for emergency laparotomy for abdominal catastrophe (e.g. bleeding, bowel perforation, abdominal compartment syndrome)
- Documented chronic pancreatitis according to the M-ANNHEIM criteria

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-05-2018
Enrollment:	54
Type:	Actual

Medical products/devices used

Generic name:	Hot AXIOS stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-01-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-02-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-10-2020
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

ID: 23568
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL63218.018.17
OMON	NL-OMON23568

Study results

Date completed:	16-04-2021
Actual enrolment:	55