

AXIOMA: Hot AXios metal stent for Infected walled-off pancreatic necrOsis Management

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23568

Source

NTR

Brief title

AXIOMA

Health condition

Pancreatitis
Necrosis
Infection
Hot AXIOS stent

Sponsors and support

Primary sponsor: Amsterdam UMC PO BOX 226601100 DD Amsterdam

Source(s) of monetary or material Support: - Boston Scientific Cooperation International
- Amsterdam UMC

Intervention

Outcome measures

Primary outcome

The need for additional endoscopic transluminal necrosectomy

Secondary outcome

- Mortality
- New-onset organ failure (cardiovascular, pulmonary, renal)
- Bleeding requiring intervention
- Perforation of a visceral organ requiring intervention and/or enterocutaneous fistula
- Pancreaticocutaneous fistula
- Biliary stricture
- Total number of radiological, endoscopic or surgical interventions for infected necrosis
- Hospital and ICU length of stay
- Exocrine and/or endocrine pancreatic insufficiency
- Medical costs

Study description

Background summary

Infected (peri)pancreatic necrosis is a life-threatening complication of acute pancreatitis. Current guidelines recommend a step-up approach in these patients, starting with catheter drainage, and if necessary, followed by a minimal invasive necrosectomy. Recent literature demonstrated no difference in mortality and major morbidity between the endoscopic and surgical step-up approach for infected necrotizing pancreatitis. However, the endoscopic step-up approach resulted in shorter hospital stay and less pancreatic fistulas. These findings suggest that the endoscopic step-up approach should be the preferred treatment modality in patients with infected necrotizing pancreatitis. The use of lumen-apposing metal stents (LAMS), like the Hot-AXIOS stent, might optimize endoscopic drainage even more and reduce the need for additional endoscopic transluminal necrosectomy and its associated morbidity and costs.

This will be investigated in the AXIOMA study, a prospective multicenter study performed in the centers of the nationwide Dutch Pancreatitis Study Group. This cohort of patients will be compared to the 51 endoscopically treated patients of the Dutch TENSION trial.

Study objective

The use of LAMS (lumen-apposing fully covered self-expanding metal stents) will optimize endoscopic drainage in patients with infected necrotizing pancreatitis, and therefore reduce the need for additional endoscopic necrosectomy and its associated morbidity and costs.

Study design

1. 6 weeks: MRI/MRCP (before 2.)
2. 6 weeks: Hot AXIOS-stent removal
3. Follow-up 3 months: exocrine and endocrine pancreatic function, questionnaires (SF-36, EQ-5D, SF-HLQ)
4. Follow-up 6 months: MRI/MRCP, exocrine and endocrine pancreatic function, questionnaires (SF-36, EQ-5D, SF-HLQ)

Intervention

Endoscopic transluminal drainage with the Hot AXIOS stent

Contacts

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Eligibility criteria

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 controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped

Start date (anticipated):	31-05-2018
Enrollment:	52
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	10-02-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50645
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6878
NTR-old	NTR7056
CCMO	NL63218.018.17
OMON	NL-OMON50645

Study results