

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23568

Bron

NTR

Verkorte titel

AXIOMA

Aandoening

Pancreatitis
Necrosis
Infection
Hot AXIOS stent

Ondersteuning

Primaire sponsor: Amsterdam UMC PO BOX 226601100 DD Amsterdam

Overige ondersteuning: - Boston Scientific Cooperation International
- Amsterdam UMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The need for additional endoscopic transluminal necrosectomy

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

Endoscopic transluminal drainage with the Hot AXIOS stent

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- ≥ 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	31-05-2018
Aantal proefpersonen:	52
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	10-02-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50645

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten