Transluminal drainage of PAncreatic fluid collections using a self-expandable metallic sTENT

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To perform a pilot study to evaluate safety and efficacy of using a covered self-expandable metallic stent for transluminal endoscopic drainage of a pancreatic fluid collection.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON41481

Source
ToetsingOnline

Brief title
PATENT

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
pancreas vocht collectie

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: drainage, pancreatic fluid collection, recurrence, timing

Outcome measures

Primary outcome

The primary endpoints are safety and efficacy.

Secondary outcome

• Removability of covered self-expendable metallic stent after PFC resolution

• Number of complications

• Number of stent migrations

• *Ease of use* measured as the scope-in and scope-out time interval during the procedure

Study description

Background summary

Patients with an acute or chronic pancreatitis which is complicated by a pancreatic fluid collection is preferably treated by endoscopic drainage with transluminal stents. Endoscopic drainage is performed by placement of at least 1 or more transluminal double pigtail stents. Drainage by this type of stents is succesful in 85% of cases. Despite occlusion the efficacy is determined by the fistula created by the stents. A larger diameter of the fistula would cause a faster and more effective drainage as is known for the surgical cystenterostomy. Using self-expandable metallic stents to create a large transluminal fistula is described in only a few studies. To determine whether the use of a large diameter SEMS can earn a place in the tranluminal treatment of PFCs we will perform a prospective trial with the aim to evaluate the safety and efficacy of the diabolo shaped Niti-S SE covered stent in the endoscopic treatment of PFCs.

Study objective

To perform a pilot study to evaluate safety and efficacy of using a covered self-expandable metallic stent for transluminal endoscopic drainage of a

pancreatic fluid collection.

Study design

We will conduct a propective cohort pilot study in which 20 patients with a symptomatic pancreatic fluid collection in the setting of acute or chronic pancreatitis will be included. Patients will undergo a transluminal endoscopic drainage of the pancreatic fluid collection with placement of a covered self-expandable metallic stent.

Intervention

Patients will be treated under conscious sedation or with Propofol. Prior to the procedure prophylactic (broad spectrum) antibiotics will be administered. A linear echoendoscope will be introduced after which the PFC will be visualised. Color Doppler ultrasound can be used to identify regional vasculature. Using a 19 G needle the PFC will be punctured from the stomach or the duodenum. After puncturing, a fluid sample will be collected and send for analysis (amylase, CEA). A 0.035-inch guidewire will be introduced through the needle and coiled into the cyst under fluoroscopic and EUS guidance. After removal of the needle a 10 Fr cystotome will be introduced in order to enlarge the fistula. Additionally, balloon dilation of the fistula using a 6 mm or 8 mm balloon will be performed. The balloon will be exchanged for a silicone covered self-expandable nitinol stent, 16 mm in diameter, 20 mm length (Niti S SEMS, Taewoong Medical). Patients will be admitted to the hospital for one night.

Study burden and risks

Risks of participation could be stent migration into the cyst which can mean additional interventions. In case of complications the gastroenterologist will decide to re-intervene endoscopically and if necessary decide to remove the stents prematurely. The burden of participating patients will be 1 office visit.

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

• Patient over 17 years
• Symptomatic pancreatic fluid collection that requires endoscopic drainage

Exclusion criteria

• Infected pancreatic necrosis
• Recurrence of prior treated pancreatic fluid collection
• Not fulfilling standard criteria to undergo PFC drainage according to local guidelines
• ASA class IV or V

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-08-2013
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Niti S stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	31-01-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-12-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-03-2015

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-07-2015
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

No registrations found.

In other registers

Register	ID
CCMO	NL40756.018.12