Covered self-expandable metal stents for benign biliary strictures: a prospective mulitcenter trial

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The aim of this study is to determine safety, patency of placement and long term symptom-free outcome of a covered self expandable metal stent in patients with a benign CBD stricture.

Ethical review	Not approved
Status	Will not start
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON32140

Source
ToetsingOnline

Brief title
PLAMET 2

Condition

- Gastrointestinal stenosis and obstruction

Synonym
benign biliary obstruction, CBD obstruction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: benign biliary stricture, covered self expandable metal stent, safety, stent patency

Outcome measures

Primary outcome

Initial technical result; stent patency, complications, technical result of

stent removal and long-term outcome

Secondary outcome

Not applicable

Study description

Background summary

Benign biliary strictures occur most frequently after surgical procedures, chronic pancreatitis or iatrogenic ampullary stenoses. Traditionally, surgery has been the treatment of choice. A less invasive alternative is endoscopic or percutaneous dilatation with plastic stent placement. The major drawbacks of plastic stents are the need for multiple procedures to avoid cholangitis caused by stent clogging and to dilate in a stepwise fashion.
As a consequence of their larger diameter, uncovered self expandable metal stents (SEMS) have been introduced in effort to maintain duct patency for a longer period than with plastic stents, which will result in fewer procedures. Uncovered SEMS have been shown to be effective, but long term stent patency is limited due to tissue ingrowth through the mesh in uncovered stents. Furthermore, surgical management of patients with SEMS is difficult, as these devices can hardly be removed due to embedding into the biliary wall. These disadvantages of uncovered SEMS have led to the development of covered SEMS, with the potential benefit that these stents can be removed. In addition, covered stents, because of their diameter, may serve as a dilator. This could avoid stepwise (every 3 months for one year) dilatation,as is done with plastic stents, unnecessary and eliminates the necessity of multiple procedures. Limitate prospective studies on the use of covered SEMS in patients with benign CBD obstruction have been performed.

Study objective

The aim of this study is to determine safety, patency of placement and long

term symptom-free outcome of a covered self expandable metal stent in patients with a benign CBD stricture.

Study design

A prospective multicenter study in 25 Dutch centres.

Intervention

After informed consent, all patients included in this study will be given a covered SEMS following preceding dilation during ERCP.

Study burden and risks

During ERCP a covered SEMS will be placed. Prior to stent placement the biliary stricture will be dilated to a diameter of 10 Fr, if indicated to advance the SEMS introduction device.Dilation and stent placement will be performed during ERCP. One week after stent placement serum aspartate aminotransferase (ASAT), alanine aminotransferase (ALAT), alkaline phosphatise (AP), gamma-glutamyl transferase (*-GT) and bilirubin will be measured. After 3 months, ERCP will be performed to remove the covered SEMS and another blood sample will be collected to measure ASAT, ALAT, AP, *-GT and bilirubin. One week, 3, 6, and 9 months after stent removal another blood sample will be collected to measure the same parameters. In case of signs of symptoms of CBD obstruction, an ERCP will be performed and a plastic stent will be placed.

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

- Benign CBD obstruction confirmed with a CT scan and/or EUS
- Serum bilirubin >50 micromol/L or clinical symptoms of a biliary stricture
- Age > 18 years
- Written informed consent

Exclusion criteria

- Known history with hepatico-jejunostomy or choledocho jejunostomy or choledocho duodenostomy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start

Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	Stent
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	18-11-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL23058.041.08