The use of covered expandable stents with a proximal lasso to resolve benign post-surgical biliary strictures

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To investigate feasibility, safety, and effectiveness of covered expandable stents with a proximal lasso to resolve benign post-surgical strictures.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bile duct disorders
Study type	Interventional

Summary

ID

NL-OMON31319

Source
ToetsingOnline

Brief title
Covered expandable stents with proximal lasso in benign biliary stenosis

Condition

- Bile duct disorders
- Hepatobiliary therapeutic procedures

Synonym
Benign post surgical biliary strictures

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Fujinon Medical Holland BV, Veenendaal, Netherlands,Life Partners Europe, Bagnolet, France,MI Tech Co.

LTD., Seoul Korea,MI Tech Co. LTD.;Seoul Korea

Intervention

Keyword: Benign, Biliary stent, Biliary stricture

Outcome measures

Primary outcome

Successful removal of covered expandable stent using the proximal lasso.

Secondary outcome

Stricture resolution, ease of stent removal, stent patency, migration rate, integrity of the covering membrane after stent removal, number of endoscopic procedures, removability of covered expandable stent at surgery (if surgery is indicated)

Study description

Background summary

Endoscopic therapy is regarded as the initial therapy of choice to treat benign biliary strictures. Based on the intensity of the treatment with plastic stents, efforts continue to improve the endoscopic treatment of benign strictures. The use of a removable coated expandable metal stent may be promising in this respect. Removal of the expandable metal stent is however complicated in some cases. Snare techniques and a distal lasso have been used anecdotally, but in both the whole surface area of the stent must detach from the common bile duct at the same time. This problem could be overcome by using a proximal lasso; thereby the stent is removed inside-out and level by level.

Study objective

To investigate feasibility, safety, and effectiveness of covered expandable stents with a proximal lasso to resolve benign post-surgical strictures.

Study design

Non-randomised prospective follow-up study with 3 sequential groups of 8

patients each.

Intervention

In all patients a covered expandable biliary stent with a proximal lasso will be placed to resolve benign post-surgical strictures. In the first group of 8 patients the stent will be removed after 2 months, in the second group after 3 months and in the third group after 4 months.

Study burden and risks

Risks of the endoscopic intervention inserting the covered expandable stent is comparable with placement of plastic stents. However, current plastic stent therapy implies far more endoscopic procedures (ERCP*s) than treatment with a covered expandable stent. Consequently the risk of complications of ERCP and cumbersomeness for patients will be relatively low. Although the covered expandable stent with proximal lasso is designed to be easily removable and experience with removal has been obtained in esophageal stenting, the possibility remains that a covered expandable stent can not be retrieved from the bile duct. In such a case the patient will be referred for surgery.

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 biliary stricture due to a surgical injury
* Proximal extend of the stricture limited to 2 cm below the liver hilum

Exclusion criteria

* More than 1 plastic stent traversing the stenosis
* Refusal to sign informed consent

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2007
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Generic name:	Hanaro fully covered expandable biliary stent equipped with

	a distal and proximal lasso
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Application type:	First submission
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	NL16620.018.07