A multi-center, single arm, prospective study of the WallFlex biliary partially covered stent for the palliative treatment of malignant bile duct obstruction.

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The overall objective of this study is to assess the functionality of the WallFlex Biliary Partially-covered stent as a palliative treatment for malignant bile duct obstruction.

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON30737

Source
ToetsingOnline

Brief title
WallFlex Biliary PC Study

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
Malignant biliary obstruction, malignant obstruction of the biliary tract

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific Corporation
Source(s) of monetary or material Support: Boston Scientific Corporation

Intervention

Keyword: Malignant bile duct obstruction., Palliative, Stent

Outcome measures

Primary outcome

Adequate clinical palliation of the biliary obstruction defined as absence of recurrent biliary obstruction within 6 months or prior to death, whichever comes first. Recurrent biliary obstruction will be determined by the treating physician based on imaging of the stent and/or cholestatic symptoms and/or abnormal liver function tests.

Secondary outcome

1. Safety

2. Technical success of stent placement

3. Re-interventions

4. Clinical symptoms of biliary obstruction

5. Laboratory liver tests

6. Recurrent biliary obstructions at 1 week, 2 weeks, 1 month, 3 months and 6 months

7. Time to recurrent biliary obstruction

8. The possibility of stent removal during placement

Study description

Background summary

Common treatment of patients with malignant biliary obstruction is endoscopic stent placement. Patient with metal stents typically undergo subsequent

procedures only when a complication arises, whereas patients with plastic stents typically require subsequent procedures for stent exchange every 3 or 4 months. Studies have shown that although metal stents are initially more expensive than plastic stents, metal stents are associated with lower overall costs for patients surviving longer than 3 months.
Tumor ingrowth through the struts of the stent and overgrowth over the ends of the stent have proved to be limitations of metal stent devices. Covered metal stents were designed to prolong patency by preventing tumor ingrowth. An increased rate of stent migration is a potential issue in the use of covered stents, as the smooth surface reduces friction between teh stent and the tissue.

The WallFlex biliary partially-covered stent is being evaluated as a treatment for biilary strictures caused by malignant neoplasms and has the following features and anticipated benefits:

* Partial covering: decreased potential for tumor or tissue in-growth compared to bare metal stents
* Looped wire ends: decreased potential for tissue damage from sharp wires at stent ends
* Flared ends: decreased potential for migration
* Retrieval loop: allows the stent to be removed during the intital placement procedure

Study objective

The overall objective of this study is to assess the functionality of the WallFlex Biliary Partially-covered stent as a palliative treatment for malignant bile duct obstruction.

Study design

A multi-center, single arm, prospective study.

Intervention

Patients will be treated with a WallFlex Biliary Partially-covered stent.

Study burden and risks

The WallFlex Biliary Partially-covered Stent is not expected to present increased risk to study patients compared to previously approved and marketed metal biliary stents. The primary risks associated with metal biliary stents include: pain, bleeding, fever, nausea, vomiting, infection, inflammation, recurrent obstructive jaundice, stent occlusion, tumor overgrowth around ends of stent, tumor ingrowth through the stent, mucosal hyperplasia, cholangitis,

cholecystitis, pancreatitis, bile duct ulceration, perforation of duodenum or bile duct, stent migration, stent misplacement, death (other than that due to normal disease progression)

The study follow-up visits may be conducted by phone, however, patients will be required to have their blood drawn for liver function testing at 1 Month.
Study visits will be Screening/Baseline, Procedure, 1 Week, 2 Weeks, 1 Month, 3 Months, and 6 Months

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

Inoperable extrahepatic biliary obstruction by any malignant process.
Indicated for metal stent placement for palliative treatment of biliary stricture(s) produced by

malignant neoplasms.

Exclusion criteria

Strictures that cannot be dilated enough to pass the delivery system.
Perforation of any duct within the biliary tree.
Presence of metal biliary stent.
Patients with active hepatitis.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	08-12-2006
Enrollment:	18
Type:	Anticipated

Medical products/devices used

Generic name:	Biliary stent
Registration:	No

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	NL15022.018.06