A Multi-Center, Prospective, Randomized Study Comparing Removable, Self-Expanding Metal Stents to Plastic Stents for the Treatment of Benign Biliary Strictures Secondary to Chronic Pancreatitis

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To compare the use of Self Expanding Metal Stents (SEMS) to plastic stents for the treatment of benign biliary strictures secondary to chronic pancreatitis as it pertains to stricture resolution rates, complication rates and number of ERCP...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON39165

Source
ToetsingOnline

Brief title
WallFlex Biliary FC Chronic Pancreatitis RCT

Condition

- Gastrointestinal stenosis and obstruction
- Endocrine neoplasms benign

Synonym
benign blockage of bile duct due to chronic pancreatitis or benign biliary obstruction due to chronic pancreatitis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Benign Biliary Strictures, Chronic Pancreatitis

Outcome measures

Primary outcome

Primary Endpoint: Stricture resolution at 24 months.

Stricture resolution at 24 months is defined by the following two criteria

being met:

• Absence of re-stenting after the per-protocol stenting period through the 24

month visit

• Absence of cholestasis at the 24 month visit, defined as alkaline phosphatase

level not exceeding 2 times the level at completion of the per-protocol

stenting period

Secondary outcome

1. Occurrence of adverse events related to the stent and/or the stent placement

or removal procedures

2. Number of ERCP procedures through 24 months after initial stent placement

3. Ability to deploy the stent(s) in satisfactory position

4. Stent removal:

- Ability to remove the stent(s) without serious stent removal related adverse

events at each procedure involving removal of stent(s) (technical success at removal)

- Complete distal migration without serious stent removal related adverse events

5. Liver Function Tests (LFT*s):

- Baseline LFTs compared to LFTs taken at the time of original plastic stent placement for any subject with a prior plastic stent.

- LFT improvement at month 1 compared to baseline LFTs (and/or compared to LFTs taken at the time of original plastic stent placement for any subject with a prior plastic stent)

- LFTs at month 24 compared to LFTs at removal of last stent (applicable for subjects who had not been re-stented at time of month 24 visit)

6. Health Economic Endpoints:

o Number of outpatient procedures

o Number of hospitalizations

o Duration of hospitalizations

o Length of procedures

o Number of devices

Study description

Background summary

Benign strictures of the common bile duct may occur in approximately 3%-45% of subject with chronic pancreatitis. Previously, surgery was typically performed for subjects with chronic pancreatitis, but is associated with high morbidity and mortality. Chronic pancreatitis subjects are also typically poor surgical candidates due to concomitant malnutrition, cirrhosis or portal hypertension. Non-surgical candidates will usually undergo endoscopic treatment with one or

more multiple plastic stents placed, resulting in adequate short-term resolution of pancreatitis but can be associated with high occlusion and migration rates and poor long-term results.
Plastic stents, which are intended for temporary placement and are removable, have become standard of care for endoscopic treatment of benign strictures due to chronic pancreatitis. More recently, physicians are using self-expandable metal stents (SEMS) for treatment of and removal from such strictures due to the long-term patency, lower occlusion and obstruction rates, of metal stents compared to single or multiple plastic stents.
This study is intended to help determine which currently available treatment methodology, multiple plastic stents or a single metal stent, is a better option in terms of safety and efficacy for patients diagnosed with benign biliary stricture secondary to chronic pancreatitis.

Study objective

To compare the use of Self Expanding Metal Stents (SEMS) to plastic stents for the treatment of benign biliary strictures secondary to chronic pancreatitis as it pertains to stricture resolution rates, complication rates and number of ERCP procedures during 24 months.

Study design

This study is designed as a multi-center, prospective, randomized study. Ten to 15 sites will participate, and enrollment of 164 patients is planned. The proposed duration of the study is approximately 4 years (2 months for enrollment, plus 2 years to complete follow-up).

Intervention

Patients who are consented and meet inclusion/exclusion criteria will undergo stenting procedure(s) with either the WallFlex Biliary Fully Covered Stent System or standard of care plastic stents (1:1 randomization). Per-protocol, patients randomized to metal stents will have a metal stent in place for 12 months at which point it will be removed via ERCP. Patients randomized to plastic stents will have their stents exchanged/bile ducts calibrated at 4 and 8 months and stents removed at 12 months via ERCP.

Study burden and risks

Potential Complications associated with Metal Stent Placement and Removal:
As per the commercial DFU included with the study devices, the potential complications associated with metal stent placement include, but are not limited to:
• Pain
• Bleeding

• Fever
• Nausea
• Vomiting
• Infection
• Inflammation
• Stent occlusion
• Tumor overgrowth around ends of stent
• Tumor ingrowth through the stent
• Mucosal hyperplasia
• Cholangitis
• Cholecystitis*
• Pancreatitis
• Ulceration of duodenum or bile duct
• Perforation of duodenum or bile duct
• Stent migration
• Death (other than that due to normal disease progression)
• Stent misplacement
• Perforation of the gallbladder due to the stent covering the cystic duct*
• Stent Fracture
• Hepatic abscess
*Note: In a small clinical trial of this device, two out of four (50%) subjects who had a stent placed across the cystic duct developed cholecystitis. One of these subjects suffered a perforated gallbladder due to the stent covering the cystic duct, requiring a drain to be placed.

As per the commercial DFU included with the study devices, potential complications associated with stent removal include, but are not limited to:
• Pain
• Bleeding
• Fever
• Nausea
• Vomiting
• Infection
• Inflammation
• Recurrent obstructive jaundice
• Mucosal hyperplasia
• Cholangitis
• Cholecystitis
• Pancreatitis
• Ulceration of duodenum or bile duct
• Perforation of duodenum or bile duct
• Death (other than that due to normal disease progression)
• Impaction to the common bile duct wall

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

• Age 18 or older
• Willing and able to comply with the study procedures and provide written informed consent to participate in the study
• Chronic pancreatitis
• Symptomatic bile duct stricture (defined by cholangitis or persistent jaundice for at least one month or cholestasis associated with at least 3 times normal alkaline phosphatase levels) documented at time of enrollment for naive stricture or at the time of prior plastic stent placement - in strictures that had one prior plastic stent inserted.
• Common bile duct stricture based on imaging assessment of dilatation of the common and/or intrahepatic bile ducts

Exclusion criteria

• Biliary stricture of benign etiology other than chronic pancreatitis
• Prior biliary metal stent or any plastic stenting other than one plastic stent of 10Fr or less for 6 months or fewer.
• Developing obstructive biliary symptoms associated with an attack of acute pancreatitis
• Biliary stricture of malignant etiology
• Stricture within 2 cm of common bile duct bifurcation
• Known bile duct fistula or leak
• Subjects for whom endoscopic techniques are contraindicated
• Known sensitivity to any components of the stent or delivery system
• Symptomatic duodenal stenosis (with gastric stasis)
• Participation in another investigational study within 90 days prior to consent
• Investigator Discretion

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2013
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	WallFlex Biliary RX Fully Covered Stent System / Comparator - standard of practice plastic stents
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	12-10-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-03-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL39896.078.12