Fully Covered Self Expanding Metal Stents (FCSEMS) for Pancreatic Duct Strictures in Patients with Chronic Pancreatitis

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The objective of this study is to prospectively document the performance of a fully covered self expanding metal stents (FCSEMS) for treatment of pancreatic duct strictures in patients with painful chronic pancreatitis.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45976

Source
ToetsingOnline

Brief title
WallFlex Pancreatic Pivotal

Condition

- Other condition
- Exocrine pancreas conditions
- Gastrointestinal therapeutic procedures

Synonym
inflammation of the pancreas, Pancreatitis

Health condition

Chronic pancreatitis

Research involving
Human

Sponsors and support

Primary sponsor: Medische Hulpmiddelen Industrie
Source(s) of monetary or material Support: Boston Scientific Corporation is the sponsor of this research trial.

Intervention

Keyword: Chronic Pancreatitis, WallFlex

Outcome measures

Primary outcome

The primary effectiveness endpoint is pain reduction at 6 months after removal

of the WallFlex stent or 6 months after observation of migration of the stent.

The primary safety endpoint is the rate of related serious adverse events from

the placement of the WallFlex stent to the end of the study.

Secondary outcome

The secondary endpoints include stricture resolution, clinical status

improvement, recurrence of stricture, stent functionality, Izbicki pain score,

average daily narcotic use, ability to deploy the stent in a satisfactory

position, successful stent removal, and device event rate.

Study description

Background summary

Chronic pancreatitis (CP) is commonly defined as a chronic inflammatory process of the pancreas, characterized by irreversible morphologic changes. CP is a relatively rare disorder occurring in about 20 cases per 100,000 per year. The disease is progressive with persistent inflammation leading to damage and/or destruction of the pancreas. This chronic inflammation can lead to chronic

abdominal pain and/or impairment of endocrine and exocrine function of the pancreas. Inflammatory changes of the pancreas associated with CP may involve some or all of the following: fibrosis, calcification, pancreatic ductal inflammation, and pancreatic stone formation. Chronic pancreatitis is also associated with obstruction of the pancreatic duct secondary to strictures related to pancreatic inflammation, or benign or malignant tumors.
While pancreatic duct stones are sequelae of chronic pancreatitis, they also may be responsible for recurrent acute pancreatitis or exacerbations of chronic pain related to ductal obstruction and increased ductal pressure. Stones usually form proximal to ductal strictures and usually require a pancreatic duct sphincterotomy and stricture dilation to enable their extraction. In addition to various endoscopic techniques, extracorporeal shockwave lithotripsy (ESWL) often is necessary to break up impacted or large stones into smaller pieces suitable for removal.
In the treatment of benign pancreatic duct strictures caused by CP, the ultimate clinical objective is durable pain control without major complications. The gold standard of treatment for benign pancreatic strictures remains surgery; however, the morbidity associated with these major surgical procedures has made less-invasive endoscopic alternatives a first line approach for treatment of simple benign main pancreatic duct strictures associated with CP.
Endoscopic placement of a single or multiple plastic stents is widely used for patients with painful CP and associated dominant pancreatic duct strictures. Approximately half of patients with severe CP who undergo endoscopic treatment require pancreatic stent placement in order to relieve obstruction of the main pancreatic duct caused by a dominant stricture, usually located in the pancreatic head. Transpapillary pancreatic duct stent placement in symptomatic CP associated with pancreatic duct stricture has been shown, in multiple studies, to be effective, with long-term pain relief achieved in approximately two thirds of patients.
Placement of SEMSs in the pancreatic duct may offer advantages over multiple plastic stents. Although literature regarding pancreatic SEMS is scarce, some preliminary conclusions based on biliary SEMS used for the treatment of malignant biliary obstruction may also be theoretically applicable to pancreatic SEMS. By analogy with the biliary tract, the larger diameter of SEMSs may offer longer-lasting drainage of the main pancreatic duct. Conventional plastic pancreatic stents typically remain patent for less than 2 months, likely because the lumen is small (5 F - 7 F); whereas, the larger lumens of SEMSs may potentially remain patent for extended periods.
Uncovered SEMSs have been successfully placed in the pancreatic duct for malignant conditions; however, placement of uncovered SEMSs for treatment of benign pancreatic diseases has been unsatisfactory because of tissue ingrowth through the wire mesh and migration. Moreover, difficult removability of a malfunctioning uncovered metal stent is problematic. In contrast, covered metal stents have the advantage of prevention of tissue hyperplasia and easy removability compared with uncovered stents.
SEMSs were first reported as an alternative to plastic stenting of benign

pancreatic duct strictures in the 1990s. A study by Eisendrath and Deviere, published in1999, reported on 38 patients with CP associated with dominant stricture of the main pancreatic duct; 20 treated using an uncovered SEMSs and 18 using a partially- or fully-covered SEMSs. The authors concluded that while uncovered and partially-covered SEMSs should be avoided due to excessive tissue ingrowth, fully-covered SEMSs (FCSEMSs) showed promising long-term patency results for treatment of CP-associated pancreatic strictures compared to outcomes using plastic stents. The authors concluded that the use of FCSEMSs may reduce the number of interventions compared to plastic stenting.

Study objective

The objective of this study is to prospectively document the performance of a fully covered self expanding metal stents (FCSEMS) for treatment of pancreatic duct strictures in patients with painful chronic pancreatitis.

Study design

This study is a prospective, single arm, pre-approval study. Treatment of up to 92 patients will take place at up to 10 clinical centers. Patient who meet all eligibility criteria will receive the WallFlex Pancreatic stent for up to 6 months stent indwell and 6 months follow-up after stent removal.

Intervention

Patients will receive the WallFlex Pancreatic Stent, which will be placed in the pancreatic duct during endoscopic retrograde cholangiopancreatography and remain indwelling for up to 6 months.

Study burden and risks

The following anticipated adverse events (AE) have been identified for this study associated with the placement and removal of the study device.
* Pain
* Cholestasis
* Cholangitis
* Pancreatitis
* Secondary stricture formation
* Obstructive Jaundice
* Vomiting
* Bleeding
* Infection
* Sepsis
* Abscess Formation
* Hyperplastic Tissue Reaction
* Tissue trauma (including events such as duct injury, rupture, edema,

inflammation, impaction, laceration and necrosis)
* Pancreatic Duct Rupture
* Allergic Reaction
* Pseudocyst development
* Fever
* Death (excluding disease progression)
* Impaction to pancreatic duct wall
* Perforation with or without pneumoperitoneum
* Pseudoaneurysm

Participation in the trial may be demanding and time consuming. Additional risks may exist. Risks can be minimized through compliance with this protocol, performing procedures in the appropriate hospital environment, adherence to patient selection criteria, close monitoring of the patient*s physiologic status during research procedures and/or follow-ups and by promptly supplying the Sponsor with all pertinent information required by this protocol.

Patients may not receive any benefit from participating in this study. However, medical science and future patients may benefit from this study. Based on collected reports in literature to-date, the risk-to-benefit ratio is within reason for foreseeable risks. However, literature reports do not always capture all side effects. Observation and follow-up of patients is required as outlined in the protocol.

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

1. Age 18 or older
2. Willing and able to comply with study procedures and follow-up schedule and provide written informed consent to participate in study
3. Chronic pancreatitis induced stricture of Cremer Type IV, namely distal dominant stricture with upstream ductal dilation.
4. For patients with one prior plastic pancreatic stent: VAS Pain Score and Frequency of Pain sectors of the Izbicki pain scale at the time of placement of the plastic stent.
5. Availability of narcotic dosage for at least one month prior to baseline visit for patients who do not have a prior plastic stent or availability for one month prior to placement of prior plastic stent, where applicable.
6. VAS Pain Score of 20 at the time of study stent placement for patients with no history of pancreatic stenting. VAS Pain Score of 20 at time of initial plastic pancreatic stent for patients with history of one prior plastic pancreatic stent indwelling for 3 months or less. VAS Pain Score is captured via Izbicki pain scale.
7. Pain occuring weekly or more frequently (assessed by Frequency of Pain sector of the Izbicki pain scale).
8. Minimum 5 mm diameter of dilated duct immediately upstream of pancreatic duct stricture
9. Prior clearance of pancreatic stones where needed
* If pancreatic duct stone clearance prior to placement of the study stent includes ESWL, then a plastic stent should be placed immediately after the ESWL procedure instead and left indwelling 1-3 months.
* If new pancreatic duct stones requiring ESWL have formed by the time of intended study stent placement, then the patient will not receive the study stent and be excluded from the study. Further treatment of the patient will be provided per standard of practice outside of the study. In case the study stent is not placed during the same session in which the plastic stent is removed, the pain score needs to be collected again prior to study stent placement.
10. Prior endoscopic pancreatic sphincterotomy (EPS), historically or to be provided at time of SEMS placement as applicable

Exclusion criteria

1. Pancreatic or peri-ampullary cancer with or without pancreatic duct strictures caused by malignancy
2. Biliary strictures caused by chronic pancreatitis
3. Perforated duct
4. Ansa pancreatica
5. Presence of pancreatic cysts suspected to be cystic tumor or requiring transmural drainage
6. Duodenal/groove pancreatitis
7. Pancreatic duct stenoses not located in the head of the pancreas
8. Failed access during an attempted ERCP on a prior date at the investigational center
9. History of prior side-by-side multiple pancreatic plastic and/or history of prior pancreatic metal stent(s)
10. Reported recent history of acute relapsing pancreatitis
11. Patients for whom endoscopic techniques are contraindicated.
12. Patients who are currently enrolled in another investigational study that would directly interfere with the current study, without prior written approval from the sponsor
13. Inability or refusal to comply with the follow-up schedule including patients living at such a distance from the investigational center that attending follow-up visits would be unusually difficult or burdensome

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	23
Type:	Anticipated

Medical products/devices used

Generic name:	Fully Covered Self Expanding Metal Stents

Registration:	No

Ethics review

Approved WMO Date:	12-04-2017
Application type:	First submission
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
ClinicalTrials.gov	NCT02802020
CCMO	NL57735.078.16