Biodegradable self-expandable stents for pancreatic duct strictures due to chronic pancreatitis

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The aim of this study is to investigate the safety and efficacy of biodegradable self-expandable stents in patients with a benign fibrotic pancreatic duct stricture due to chronic pancreatitis.

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

Summary

ID

NL-OMON39445

Source
ToetsingOnline

Brief title
BSPD study

Condition

- Gastrointestinal stenosis and obstruction

Synonym
Pancreatic duct obstruction, Pancreatic duct stricture

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,De firma Ella-CS,Ella-CS

Intervention

Keyword: Biodegradable stents, Chronic pancreatitis, Pancreatic duct strictures

Outcome measures

Primary outcome

The primary outcome measure is safety. Therefor, all complications will be

documented.

Secondary outcome

Secondary outcome measures are;

Successful stent placement

Stent resolution

Clinical success; pain relief

Technical success; stricture resolution

Study description

Background summary

A fibrotic pancreatic duct stricture is a common complication of chronic pancreatitis and is typically difficult to treat. Conventional endoscopic treatment consists of the sequential placement of an increasing number of plastic stents for 6 to 12 months, with 3-monthly stent exchanges. In contrast with post-operative biliary strictures, the success rate of endoscopic treatment in this patient group is much lower, and more than half of the patients will eventually undergo surgery.

Treatment with self-expandable stents seems more effective due to the larger diameter of the stent, but the unremovable nature of these metal stents makes them unsuitable for treatment of benign strictures. Therefore, biodegradable self-expanding stents would be the perfect solution for this patient group. Not only would more effective treatment prevent surgery, but also, therapy would be

more patient friendly, because it would involve less procedures.

Study objective

The aim of this study is to investigate the safety and efficacy of biodegradable self-expandable stents in patients with a benign fibrotic pancreatic duct stricture due to chronic pancreatitis.

Study design

This study is a prospective clinical intervention trial, executed in two different centers; the endoscopy department of the Erasmus University Medical Center in Rotterdam, and the Division of Gastroenterology & Hepatology of the University Hospital Leuven, Belgium

After stent placement, patients will be followed for a 1-year period, clinically and with abdominal ultrasound, at 3 monthly intervals. In addition, after 6 months, an ERCP will be performed to evaluate stent and stricture resolution.

Intervention

The intervention consists of the endoscopic placement of a biodegradable self-expandable stent to cross the pancreatic duct stricture. This stent is expected to degrade within 6 months.

Study burden and risks

The study does not cause any additional burden on patients, compared to endoscopic treatment with plastic stents. The stent placement and follow-up procedures are similar to standard clinical care. Participation will even decrease the burden, because 3-monthly stent exchange procedures are not necessary.

The risks associated with participation in the study are not expected to be any different from the complications of regular treatment with plastic stents. Patients might benefit from participation, because the chance of stricture resolution is expected to be higher. Therefor, an operation might be prevented.

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. A diagnosis of chronic pancreatitis, based on clinical symptoms in combination with morphological changes established by imaging studies (atrophy, calcifications or ductal changes) and/or pancreatic functional insufficiency.
2. A benign fibrotic pancreatic duct stricture.
3. Previous endoscopic dilatation with plastic stents for at least 6 months has failed to resolve this stricture.

Exclusion criteria

1. Age less than 18 years
2. Contra-indication for endoscopy; Roux-en-Y reconstruction
3. Suspected pancreatic malignancy
4. Limited life expectancy due to co-morbidity (< 1 year)
5. Pregnancy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-12-2012
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Biodegradable self-expandable stent
Registration:	No

Ethics review

Approved WMO Date:	08-05-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	09-12-2013
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	NL36060.078.11