Covered Stents versus Bare-Metal Stents in Chronic Atherosclerotic Gastrointestinal Ischemia

Published: 26-11-2013
Last updated: 23-04-2024

To compare the outcome of revascularisation the gastrointestinal arteries using covered stents compared to bare-metal stents in patients with CGI.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal vascular conditions
Study type	Interventional

Summary

ID

NL-OMON47639

Source
ToetsingOnline

Brief title
Covered Stents versus Bare-Metal Stents

Condition

- Gastrointestinal vascular conditions
- Lifestyle issues
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
treatment of bowel ischemia., treatment of mesenteric ischemia

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

Intervention

Keyword: arterial occlusive disease, bare metal stent, endovasculair treatment, polytetrafluoroethylene covered stent

Outcome measures

Primary outcome

Compare the primary and secondary patency rates of covered stents versus

bare-metal stents to treat atherosclerotic CGI disease.

Secondary outcome

Freedom from restenosis, from symptom recurrence and from reintervention, and

clinical outcome in terms of quality of life and therapeutic and total costs

after 6-, 12- and 24- months after stent implantation.

Restenosis is defined as >50% intra-stent stenosis regardless of whether the

patient has clinical symptoms.

Symptom recurrence is defined as occurrence of clinical symptoms typical for

CGI regardless of stent patency

Re-intervention is defined as intervention due to symptom occurrence in the

presence of >50% intra -stenosis, either a reimplantation of stent or a

surgical procedure.

Study description

Background summary

Symptomatic chronic atherosclerotic gastrointestinal ischemia (CGI) is an uncommon, potentially underdiagnosed condition caused by fixed stenosis or occlusion of in most conditions at least one of the three gastrointestinal arteries. Atherosclerosis is a predisposing factor for CGI. Clinical symptoms can vary widely. Typical symptoms are postprandial abdominal pain, unintended

weight loss and food avoidance. But atypical abdominal pain such as exercise related pain, diarrhoea and nausea can also indicate CGI. The use of endovascular techniques for revascularization of chronic stenosis and occlusions of the gastrointestinal arteries has rapidly increased and endovascular therapy with stenting has become the most common method chosen for revascularization, having replaced open surgery with its associated morbidity and mortality. Nowadays standard care in significant chronic gastrointestinal ischemia is the use of bare metal stents although the patency of these stents is not very high. According retrospective data the patency of covered stents is significantly higher compared to bare metal stents. One likely explanation for these lower restenosis and re-intervention rates observed with covered stents is the established barrier to tissue ingrowth. Only recent retrospective data about this topic is available but the expectancy in this prospective study is that the patency of covered stents is indeed higher compared to metal stents.

Study objective

To compare the outcome of revascularisation the gastrointestinal arteries using covered stents compared to bare-metal stents in patients with CGI.

Study design

A prospective, randomized controlled trial will be performed. Patients with CGI with stenosis or occlusion of at least one of the three gastrointestinal arteries and with indication of implantation of a stent, will be randomly assigned to receive a covered stent or bare-metal stent. Patient demographic data, clinical signs and symptoms will be recorded. Patients will be followed-up at 6-, 12- and 24- months with CTA to confirm stent patency and at baseline and at follow-up they will be asked to fill in the questionnaires about quality of life and effectiveness of the treatment.

Intervention

An endovascular treatment that consists of inserting a stent into the stenosed vessels.

Study burden and risks

This prospective study will provide valuable information about the primary and secondary patency rates of covered stents in endovascular treatment of atherosclerotic CGI, the quality of life of both arm of the study population and the cost-effectiveness of implantation of covered stents or bare metal stents. Complication rate of these two different stents are similar. It is expected that patients receiving a covered stent will benefit from better patency rates.
Patients have to undergo 3 additional low-dose CTA in 2 years, but CTA only

focused on the gastrointestinal arteries with a scan dose of approximately 1 mSv. The patient will receive in 10 years approximately extra 3 mSv, with an average of 1.7 mSv / year. The natural background in Netherlands is 2mSv and the natural background in U.S. is 3mSv, so basically we just increase the irradiation of the patient from natural background of Netherlands to natural background of U.S., wich makes it not more harmful than living in U.S.(8) During the study patients fill in a short, validated questionnaire once prior to and 6, 12 and 24 months after stentplacement. Filling in the questionnaire is simple and only takes 5 minutes.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients with consensus diagnostic of CGI based on a clinical meeting with

a gastroenterologist, a vascular surgeon and an interventional radiologist.
Diagnostic consensus of CGI is based on:
- Typical history (presence of postprandial pain, unexplained weight loss (>5% of normal body weight)
- Significant stenosis of >50% of at least one of the gastrointestinal arteries on a recent CTA not older than one year, with maximum slice thickness 1 mm and enhancement in aorta of 300HU
- Mucosal ischemia detedcted by VLS or tonometry
2. Patients over the age of 18 years
3. Patients who gave informed consent
4. Patients have sustained atherosclerosis.
5. Total length of stenosis < 25 mm

Exclusion criteria

1. Patients who don*t give informed consent
2. Age < 18 years
3. No stenosis detected during arteriography
4. Renal insufficiency (GFR below 30 ml/min or GFR below 60 ml/min when comorbidities relevant to kidney function present).
5. Previous stent placement in the to be treated gastrointestinal artery
6. Pregnancy
7. Celiac artery compression syndrome
8. Vasculitis

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	06-05-2015
Enrollment:	84
Type:	Actual

Medical products/devices used

Generic name:	Covered Stents
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-11-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-10-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-06-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-02-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-09-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-02-2018

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-08-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-08-2019
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
ClinicalTrials.gov	NCT02428582
CCMO	NL46337.078.13