Covered self-expandable metal stents for benign biliary strictures: a prospective multicenter trial.

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Benign biliary strictures occur most frequently after surgical procedures, chronic pancreatitis or iatrogenic ampullary stenosis. Traditionally, surgery has been the treatment of choice. A less invasive alternative is endoscopic or percutaneous...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22540

Bron
NTR

Verkorte titel
PLAMET 2 study

Aandoening

benign CBD obstruction, covered self-expandable metal stent

benigne galwegobstuctie, gecoverde metalen stent

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: UMC Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Initial technical result; stent patency, complications, technical result of stent removal and long-term outcome.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Benign biliary strictures occur most frequently after surgical procedures, chronic pancreatitis or iatrogenic ampullary stenosis. Traditionally, surgery has been the treatment of choice. A less invasive alternative is endoscopic or percutaneous dilatation with plastic stent placement. The major drawbacks of plastic stents are the need for multiple procedures to avoid cholangitis caused by stent clogging and to dilate in a stepwise fashion. As a consequence of their larger diameter, uncovered self expandable metal stents (SEMS) have been introduced in effort to maintain duct patency for a longer period than with plastic stents, which will result in fewer procedures. Uncovered SEMS have been shown to be effective, but long term stent patency is limited due to tissue ingrowth through the mesh in uncovered stents. Furthermore, surgical management of patients with SEMS is difficult, as these devices can hardly be removed due to embedding into the biliary wall. These disadvantages of uncovered SEMS have led to the development of covered SEMS, with the potential benefit that these stents can be removed. In addition, covered stents, because of their diameter, may serve as a dilator. This could avoid stepwise (every 3 months for one year) dilatation,as is done with plastic stents and eliminates the necessity of multiple procedures. A limited number of prospective studies on the use of covered SEMS in patients with benign CBD obstruction has been performed.

Objective:
The aim of this study is to determine safety, patency of placement and long term symptom-free outcome of a covered self expandable metal stent in patients with a benign CBD stricture.
Study design: A prospective multicenter study in 21 Dutch centres.

Study population:
Patients with a benign CBD obstruction as a complication of a surgical procedure, chronic pancreatitis or

(iatrogenic) ampullary stricture.

Intervention:
After informed consent, all patients included in this study will be given a covered SEMS following preceding dilation during ERCP.

Main study parameters/endpoints:
Initial technical result; stent patency, complications, technical result of stent removal and long-term outcome.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
During ERCP, a covered SEMS will be placed. Prior to stent placement the biliary stricture will be dilated to a diameter of 10 Fr, if indicated to advance the SEMS introduction device. Dilation and stent placement will be performed during ERCP. One week after stent placement serum gamma-glutamyl transferase (g-GT) and bilirubin will be measured. After 3 months, ERCP will be performed to remove the covered SEMS and another blood sample will be collected to measure g-GT and bilirubin. One week, 3, 6, and 9 months after stent removal another blood sample will be collected to measure the same parameters. In case of signs of symptoms of CBD obstruction, an ERCP will be performed and a plastic stent will be placed.

Doel van het onderzoek

Benign biliary strictures occur most frequently after surgical procedures, chronic pancreatitis or iatrogenic ampullary stenosis. Traditionally, surgery has been the treatment of choice. A less invasive alternative is endoscopic or percutaneous dilatation with plastic stent placement. The major drawbacks of plastic stents are the need for multiple procedures to avoid cholangitis caused by stent clogging and to dilate in a stepwise fashion. As a consequence of their larger diameter, uncovered self expandable metal stents (SEMS) have been introduced in effort to maintain duct patency for a longer period than with plastic stents, which will result in fewer procedures. Uncovered SEMS have been shown to be effective, but long term stent patency is limited due to tissue ingrowth through the mesh in uncovered stents. Furthermore, surgical management of patients with SEMS is difficult, as these devices can hardly be removed due to embedding into the biliary wall. These disadvantages of uncovered SEMS have led to the development of covered SEMS, with the potential benefit that these stents can be removed. In addition, covered stents, because of their diameter, may serve as a dilator. This could avoid stepwise (every 3 months for one year) dilatation,as is done with plastic stents and eliminates the necessity of multiple procedures. A limited number of prospective studies on the use of covered SEMS in patients

with benign CBD obstruction has been performed.

Onderzoeksopzet

During ERCP, a covered SEMS will be placed. Prior to stent placement the biliary stricture will be dilated to a diameter of 10 Fr, if indicated to advance the SEMS introduction device. Dilation and stent placement will be performed during ERCP. One week after stent placement serum gamma-glutamyl transferase (ƒ×-GT) and bilirubin will be measured. After 3 months, ERCP will be performed to remove the covered SEMS and another blood sample will be collected to measure ƒ×-GT and bilirubin. One week, 3, 6, and 9 months after stent removal another blood sample will be collected to measure the same parameters. In case of signs of symptoms of CBD obstruction, an ERCP will be performed and a plastic stent will be placed.

Onderzoeksproduct en/of interventie

Placement of a covered self expandable metal stent during ERCP.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Benign CBD obstruction confirmed with a CT san and/or EUS (no signs of metastases or invasive growth);

2. Serum bilirubin >50 mmol or clinical symptoms of an obstructive biliary stricture;

3. Age older than 18 years;

4. Written informed consent;

5. Stent placement feasible during ERCP.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Known previous surgical history with hepatico-jejunostomy, choledocho-jejunostomy or choledocho-duodenostomy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2009
Aantal proefpersonen:	20

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-07-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1800
NTR-old	NTR1910
Ander register	MEC UMC Utrecht / CCMO : 09-017 / NL26692.041.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A