Plastic or metal stent for malignant biliary obstructions

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25796

Source
NTR

Brief title
PLAMET study

Health condition

Malignant biliary obstruction, stent, cost/cost effectiveness, quality of life, prognosis

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

- Medical effects

Secondary outcome

- Quality of life

- Cost/Cost effectiveness

Study description

Background summary

Rationale:

Malignant extrahepatic biliary obstruction is a frequent complication of inoperable periampullary cancer and causes significant morbidity due to jaundice, cholangitis and malabsorption.
The primary goal of treatment is to relieve CBD obstruction, which can be performed by the placement of a plastic stent or self-expanding metal stent (SEMS) during Endoscopic Retrograde Cholangio-Pancreaticography (ERCP). Plastic stents are most often used because of their efficacy and low costs, however stent obstruction occurs frequently. SEMS, with a larger luminal diameter, are associated with a longer stent patency, but are more expensive. More recently, covered SEMS have been introduced to prevent tumor ingrowth. The disadvantage of covered stents is stent migration, and cholecystitis and pancreatitis caused by obstruction of the cystic duct and pancreatic duct. Until now, only a limited number of studies have compared these devices.

Objective:

To define indications for recently developed, but more expensive, self-expanding metal stents (SEMS) versus cheaper plastic stents in patients with primary or recurrent inoperable malignant extrahepatic common bile duct (CBD) obstruction, based on an individualized prognostic risk.

Study design:

a) RCT in 21 Dutch centers in 2 strata: 1. 300 patients with primary stent placement for CBD obstruction, and 2. 160 patients with recurrent CBD obstruction after previous stent placement.

b) Retrospective cohort study for prognostic model development (n>500). The prognostic model will be validated with the RCT data and provide the basis for a subgroup specific comparison of stent types according to individualized risk.
Study population: Patients with CBD obstruction due to inoperable periampullary and gallbladder cancer, and metastatic lymphadenopathy.

Intervention:

After informed consent, 300 (primary) + 160 (recurrent) patients will be randomized to:

a) plastic stent,

b) uncovered SEMS, or

c) covered SEMS in a 1:1:1 ratio.

Main study parameters/endpoints:
Medical effects, quality of life, costs/cost-effectiveness in 2 strata (primary and recurrent patients). Initially plastic stents vs. uncov. + cov. SEMS will be compared, and secondarily uncov. vs. cov. SEMS. The prognostic model will present a score to predict survival in patients with primary and recurrent CBD obstruction and will be used to guide stent choice.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: During the first 30 days after stent placement, patients will keep a diary on physical symptoms (such as fever, jaundice, pruritis, etc.). If he patient is unable to complete a diary (which may be the case if a complication develops on the first few days after stent placement), data will be collected by proxy assessment. After the first 30 days, the patients will provide these data on a weekly basis.
Patients will be followed up by home visits of a member of a team of specially trained research nurses at 14 days, 1 month, then monthly until six months after randomization, followed by two-monthly visits starting 6 months after randomization. During these visits, the diaries will be checked and HRQoL questionnaires will be completed. In addition, at 14 days blood samples will be collected for bilirubin levels. If the condition of patients allows, patients will be referred for a reintervention to treat recurrent CBD obstruction. Due to the unpredictable timing of reinterventions, it is not feasible to assess the burden of intervention for patients and informal care givers in all participating hospitals, and this will therefore be performed at least in the UMCU, and in other hospitals on a voluntary basis. Patients will be followed until death or at most for 1 year.

Study objective

Patients with a poor prognosis should get a cheaper plastic stent and patients with a longer prognosis shoud get a more expensive metal stent.

Study design

- Baseline

- 14 days

- 1, 2,3,4,5,6,8,10 and 12 months

Intervention

a. Plastic stent

b. Covered self-expandable metal stent

c. Uncovered self-expandable metal stent

Contacts

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Eligibility criteria

Inclusion criteria

1. Obstructive malignancy at the level of the extrahepatic CBD

2. Inoperability due to a poor medical condition, local irresectability or distant metastases

3. Serum bilirubin >50 micromol/L

4. Informed consent.

Exclusion criteria

1. Malignancy involving intrahepatic bile ducts and duodenum

2. Known history of cholecystitis (unless cholecystectomy has been performed)

3. WHO performance score of 4 (100% of ime in bed)

4. Unable to fill out quality of life questionnaires

5. Known history of operation of the bile ducts (unless cholecystectomy has been perfromed).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2008
Enrollment:	460
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-06-2008
Application type:	First submission

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
NTR-new	NL1312
NTR-old	NTR1361
Other	METC nummer UMC Utrecht : 07-342
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A