# Plastic or Metal Stents for Primary or Recurrent Inoperable Malignant Extrahepatic Biliary Obstruction

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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...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Gastrointestinal stenosis and obstruction |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON38333

**Source**
ToetsingOnline

**Brief title**
Plamet study

### Condition

- Gastrointestinal stenosis and obstruction

**Synonym**
CBD obstruction, malignant extrahepatic biliairy obstruction

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** Biliary obstruction, Life expectancy, Prognostic score, Stent

## Outcome measures

### Primary outcome

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.

### Secondary outcome

not applicable

# Study description

### Background summary

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. Another disadvantige is the tumour ingrowth. 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

### Study 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 26 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.

### 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.

### Study burden and risks

During the first 30 days after stent placement, patients will keep a diary on physical symptoms (such as fever, jaundice, pruritis, etc.), and self-rated health (EQ-VAS). 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 and then monthly after randomization until 6 months. After 6 months patients will be visited every 2 months. During these visits, the diaries will be checked and HRQoL questionnaires and economic evaluation questionnaires will be completed. In addition, blood samples will be collected at 14 days 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 least for 1 year.

## Contacts

**Public**
Academisch Medisch Centrum

Heidelberglaan 100
3584 CX UTRECHT
NL
**Scientific**
Academisch Medisch Centrum

Heidelberglaan 100
3584 CX UTRECHT
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

a. Obstructive malignancy at the level of the extrahepatic CBD,
b. Inoperability due to a poor medical condition, local irresectability or distant metastases,
c. Serum bilirubin >30 micromol/L and/or clinical symptoms of obstructive jaundice
d. Informed consent.

## Exclusion criteria

a. Malignancy involving intrahepatic bile ducts and duodenum,
b. Known history of pancreatitis or cholecystitis (unless cholecystectomy has been performed),
c. WHO performance score of 4 (100% of time in bed),
d. Unable to fill out quality of life questionnaires
e. Known history of operation of the bile ducts (p.a. choledochojejunostomy) unless cholecystectomy has been performed

# Study design

## Design

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 28-02-2008 |
| Enrollment: | 430 |
| Type: | Actual |

## Medical products/devices used

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| Generic name: | Stent |
| Registration: | Yes - CE intended use |

# Ethics review

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| Approved WMO Date: | 29-01-2008 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 19-08-2008 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 18-03-2010 |
| Application type: | Amendment |

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| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 16-06-2010 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 19-07-2011 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 20-12-2011 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 24-04-2012 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

# 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 | NL20815.041.07 |