PLASTIC STENTS VERSUS HEPARIN COATED PLASTIC STENTS FOR RELIEF OF MALIGNANT BILE-DUCT OBSTRUCTION

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in this project we will compare conventional 10fg plastic endoprosthesis with similar stents covalently coated with heparin

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bile duct disorders
Study type	Interventional

Summary

ID

NL-OMON32735

Source
ToetsingOnline

Brief title
The HEPCO trial

Condition

- Bile duct disorders

Synonym
biliary obstruction, jaundice

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,Cook Medical,Wilson-Cook

Intervention

Keyword: Bilairy obstruction, ERCP, Heparin coated, Stent

Outcome measures

Primary outcome

Stent patency at 3 months

Secondary outcome

1) procedural failure rate, 2) primary stent failure rate, 3) complications,

major (requiring surgery) and minor (requiring endoscopic or medical

intervention); 4) patient survival, 5) median stent patency

Study description

Background summary

Endoscopic placement of a biliary endoprosthesis is the primary palliative treatment for patients with obstructive jaundice to provide adequate drainage of bile. Two types of stents are inserted: polyethylene plastic stents and self-expandable metal stents. The major drawback of permanent biliary prosthesis is their short life span. Average stent patency of conventional plastic endoprosthesis is approximately 3 months. In conventional plastic stents clogging remains the predominant problem, occurring in 21 to 31% of cases. Several variables contribute to this clogging phenomenon, including bile viscosi¬ty, bacterial infection, stent surface, stent diameter and stent design. To date, only the stent diameter has been manipulated successful¬ly in numerous attempts to decrease stent-clogging rate. Various drug coatings have been successfully used to delay clogging in other endoprosthesis (e.g. vascular, urinary tract).

Study objective

in this project we will compare conventional 10fg plastic endoprosthesis with similar stents covalently coated with heparin

Study design

This is a single center prospective randomized study carried out in the Erasmus

MC Rotterdam. Patients with biliary obstruction caused by a non-resectable neoplasm involving the common bile duct will be randomized for placement of a 10 fg conventional endoprothesis or a 10 fg heparin mimetic coated endoprosthesis

Intervention

Endoscopic implantation of a 5 cm, 7 cm, 9 cm, or 12 cm 10 fg plastic stent, either conventional or heparin mimetic coated

Study burden and risks

Burden: informed consent procedure, sampling of venous blood at t=5 to 8 days, telphone interview at t=3 months
Risks: the relative risk of stent occlusion of the heparin coated stents is subject of this study. The risks of venous blood sampling is negectable

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

- Patients Age >= 18 years
- diagnosed with malignant bile duct obstruction
- referred for palliative stenting, or stent exchange
- after written informed consent

Exclusion criteria

candidate for surgical resection; clinical conditions that do not allow ERCP with sphincterotomy such as uncorrectable coagulopathies, pyloric or duodenal obstruction; stenosis extending into the left or right hepatic duct; periampullary lesions, within 2 cm from the papilla; patients with a history of heparin-induced thrombocytopenia

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):	28-11-2008
Enrollment:	90
Type:	Actual

Medical products/devices used

Generic name:	biliairy endoprosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-11-2008
Application type:	First submission
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	NL24805.078.08