Endobiliary radiofrequency ablation as treatment for occluded extra-hepatic biliary metal stents: a prospective multicenter feasibility study.

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To evaluate safety and efficacy of endobiliary RFA as a treatment for biliary SEMS occlusion caused by tissue ingrowth.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38754

Source
ToetsingOnline

Brief title
Endobiliary RFA for occluded extra-hepatic biliary SEMS

Condition

- Other condition
- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

Synonym
malignant extra-hepatic biliary obstruction

Health condition

pancreascarcinoom

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: biliary SEMS, cholangiocarcinoma, endobiliary RFA, pancreatic carcinoma

Outcome measures

Primary outcome

Biliary patency, defined as the time period between study intervention and

biliary re-obstruction.

Secondary outcome

technical success; clinical success; complications; hospitalisation; median

survival

Study description

Background summary

Patients with unresectable malignant bile duct obstruction with a life expectancy longer than 3 months are usually treated with self-expandable metal stents (SEMSs) to ensure continued biliary drainage. However patency of these stents is limited due to stent occlusion, which is mainly caused by tissue ingrowth. This complication requires re-intervention in the majority of cases, which consists of insertion of an additional biliary stent (stent-in-stent) or percutaneous biliary drainage. Endobiliary applied radiofrequency ablation (RFA) is a relatively new endoscopic technique that might be used to clear biliary SEMS that are occlude by tissue ingrowth.

Study objective

To evaluate safety and efficacy of endobiliary RFA as a treatment for biliary

SEMS occlusion caused by tissue ingrowth.

Study design

Multicenter non-randomized prospective open-label feasibility study

Intervention

Application of endobiliary RFA with the HabibTM EndoHPB device at the site of biliary obstruction during 2 minutes at a power setting of 7 Watt.

Study burden and risks

Very few complications should be expected with regards to the insertion of the EndoHPB catheter over a guidewire into the CBD, which should be no different compared to other standard catheters used during endoscopic retrograde cholangiopancreatography (ERCP). On activation of EndoHPB, the luminal use of RFA is intended to produce local coagulative necrosis of the tissue that occludes the biliary SEMS. Potential complications associated with the local application of heat include damage to surrounding healthy tissue leading to perforation, biliary leak or abscess formation. These complications have not been found in previous clinical studies and risks are minimized by using the power settings determined in an in vivo porcine model.
Patients may experience the study follow-up calls as a burden. A potential benefit of endobiliary RFA may be a prolonged biliary patency, which could eventually be reflected in better quality of life and a low number of long-term complications.

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 with unresectable malignant common bile duct obstruction caused by pancreatic head carcinoma or distal cholangiocarcinoma who have been treated previously with a biliary uncovered SEMS
• Recurrent biliary obstruction caused by SEMS occlusion due to tissue ingrowth, requiring treatment
• A clinical diagnosis of obstructive jaundice in combination with a bilirubin level of >40 µmol/L and

Exclusion criteria

• Patients with a (malignant) biliary obstruction due to other causes than pancreatic head cancer or cholangiocarcinoma
• Evidence of new additional more proximally located biliary strictures
• Clinical suspicion of cholangitis, defined as biliary obstruction in combination with fever (temperature >= 38,5°C)
• Presence of a plastic stent in the common bile duct.
• Patients who are unable to undergo ERCP due to their medical condition
• Patients suffering form concurrent gastric outlet obstruction
• Patients with a cardiac pacemaker
• Patients with a WHO performance score of 4

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Habib EndoHPB Catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	26-04-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20857
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL43040.018.12
OMON	NL-OMON20857