Endoscopisch toegediende radiofrequente ablatie als behandeling van een verstopte metalen galwegstent

No registrations found.

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

Summary

ID

NL-OMON20857

Source
NTR

Health condition

pancreatic carcinoma
cholangiocarcinoma
malignant biliary obstruction
biliary metal stent occlusion

pancreascarcinoom
cholangiocarcinoom
maligne galwegobstructie
biliaire metalen stent occlusie

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

Secondary stent patency, defined as time period (days) between RFA application and need for re-intervention for signs and symptoms of recurrent biliary obstruction.

Secondary outcome

• Technical success, defined as successful introduction of the EndoHPB catheter across the stricture and successful application of RFA at the site of stricture

• Clinical success, defined as drop in bilirubin by 50% at 2 weeks after RFA application.

• The number of complications. Complications will be graded as either intervention-related or non-intervention-related (Serious) Adverse Events ([S]AE's). An independent expert panel (composed out of two gastroenterologists with extensive ERCP experience) will decide upon intervention-relatedness. Examples of intervention-related (S)AE's are: perforation, bleeding, local abscess formation, liver infarction, cholangitis, pancreatitis, aspiration pneumonia, cardiorespiratory insufficiency during endoscopy.

• Median procedure related hospitalization (days)

• Median survival (days)

Study description

Background summary

N/A

Study design

Baseline

Every 2 weeks following RFA treatment by telepone for a maximum of 6 months of follow-up.

Intervention

Application of endobiliary RFA via ERCP with the HabibEndoHPB probe (EMcision Limited, London, UK) at the site of biliary SEMS obstruction for a duration of 2 minutes at a power setting of 7 Watt.

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Eligibility criteria

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 SEMS

• Recurrent biliary obstruction caused by SEMS occlusion due to tissue in- or overgrowth, requiring treatment

• A clinical diagnosis of obstructive jaundice in combination with a bilirubin level of > 40 µmol/L and

• Age 18 years or older

• Informed consent

Exclusion criteria

Baseline:

• 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

• Patients with a poor mental condition or mental retardation, unable to understand the nature and possible consequences of the study

Endoscopic:

• Failure to reach the ampulla of Vater.

• Failure to place a guidewire across the stricture.

• Re-obstruction not caused by tumour in- or overgrowth

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-08-2013
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion
Date: 18-07-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38754
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3911
NTR-old	NTR4081
CCMO	NL43040.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38754

Study results

Summary results
N/A