

Uncovered self-expandable metallic stent for preoperative biliary drainage in patients with resectable perihilar cholangiocarcinoma

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Metal stents are safe and a feasible for preoperative biliary drainage for resectable perihilar cholangiocarcinoma

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21193

Bron

NTR

Verkorte titel

UMBRELLA

Aandoening

Perihilar cholangiocarcinoma

Ondersteuning

Primaire sponsor: None

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of this study is to assess the feasibility of ucSEMS placement in patients with resectable pCCA defined as:

- At least 70% of patients with technical successful ucSEMS placement, that is:
 - o Placed in the segment(s) to be drained as determined by the multidisciplinary meeting, with a preferred margin of at least 1 cm proximally and distally across the stenosis
 - o Bilirubin decrease of at least 20% after 7 days
 - o No need for additional biliary drainage intervention (ERCP and/or PTCD)

Toelichting onderzoek

Achtergrond van het onderzoek

Biliary drainage in patients with perihilar cholangiocarcinoma is often performed by endoscopic placement of plastic or metal stents. Preoperatively this is mostly limited to plastic stents, but these are known to have limited patency time. The uncovered self-expanding metal stent allows for more rapid biliary decompression and has a reduced occlusion rate when compared to plastic stents. However, there is limited published evidence about the application of ucSEMS in the preoperative setting.

Doel van het onderzoek

Metal stents are safe and a feasible for preoperative biliary drainage for resectable perihilar cholangiocarcinoma

Onderzoeksopzet

Imaging, ERCP (Intervention), surgery (if performed)

Onderzoeksproduct en/of interventie

ucSEMS placement by ERCP

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- High suspicion of resectable pCCA on imaging (as determined by the multidisciplinary hepatobiliary team, with or without histopathological confirmation) And
- Preoperative endoscopic drainage is indicated (as determined by the multidisciplinary hepatobiliary team) And
- Written informed consent according to ICH/GCP, and national/local regulations. And
- Age > 18 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients who underwent previous drainage procedures by endoscopy with plastic stent placement or percutaneously with an (internalized) biliary catheter; And
- Bismuth type I pCCA (as determined by the multidisciplinary hepatobiliary team); And
- Prior diagnosis of Primary Sclerosing Cholangitis (PSC)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 05-07-2021
Aantal proefpersonen: 10
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 05-07-2021
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9600
Ander register	METC EMC : MEC-2021-0420

Resultaten