EUS-guided choledochoduodenostomy (versus ERCP) for primary drainage of malignant distal biliary obstruction: a pilot study

Gepubliceerd: 28-09-2021 Laatst bijgewerkt: 15-05-2024

A 95% technical success rate is expected

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

Samenvatting

ID

NL-OMON23030

Bron
NTR

Verkorte titel
SCORPION-pilot

Aandoening

Adult patients with malignant distal biliary obstruction that require biliary decompression.

Ondersteuning

Primaire sponsor: Amsterdam UMC
Overige ondersteuning: Pending

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To establish the technical success of EUS-CD for the primary drainage of malignant distal biliary obstruction. Technical success is defined as successful creation of a choledochoduodenostomy using a LAMS, which is directly confirmed by a cholangiogram.

Toelichting onderzoek

Achtergrond van het onderzoek

Endoscopic retrograde cholangiopancreatography (ERCP) has been the primary approach to decompress the bile duct in patients with a malignant biliary obstruction. In spite of extensive experience with this technique in the Netherlands the technical success of ERCP in these patients is only 75%. Complications of ERCP such as post-procedural pancreatitis (3,5 - 10%), bleeding (0,3 - 9%), cholangitis (0,5 - 3%), cholecystitis (0,5 - 5,2%) and perforation (0,08-0,6%) are also not uncommon. Endoscopic ultrasound-guided choledochoduodenostomy (EUS-CD) obviates the need to reach the papilla and, in contrast to ERCP, is feasible in patients with duodenal obstruction. By bypassing the pancreas and the tumour EUS-CD does not lead to post-procedural pancreatitis. Three randomized controlled trials in international expert centres in North-America and Asia have compared EUS-CD versus ERCP which showed similar technical success, but lower adverse events and longer stent patency in EUS-BD. More data is needed to assess whether EUS-CD is indeed superior to ERCP as primary drainage strategy in patients with distal malignant biliary obstruction. In this pilot study the effectiveness and safety of EUS-CD will be evaluated in our tertiary referral center, and if satisfactory, a multicentre randomized controlled trial will be initiated.

Doel van het onderzoek

A 95% technical success rate is expected

Onderzoeksopzet

Baseline: bilirubin levels
2 weeks after the procedure: consultation and bilirubin levels
4 weeks after the procedure: consultation and bilirubin levels
Every 3 months after the procedure: consultation and bilirubin levels

Patients will be followed up until pancreaticoduodenectomy or death.

Onderzoeksproduct en/of interventie

EUS-guided choledochoduodenostomy

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Radiographically (CT or EUS) distal malignant bile duct obstruction.
- Histology or cytology proven malignancy of the primary tumour or metastasis; onsite cytology evaluation after EUS guided fine-needle sampling that is highly suspected of a malignancy suffices.
- Indication for biliary drainage; in case of an resectable tumour this should be discussed during a clinical multidisciplinary meeting.
Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Age < 18 year.
- Surgically altered anatomy after previous gastric, periampullary or duodenal resection.
- Cancer extending into the antrum or proximal duodenum.
- Extensive liver metastases.
- WHO performance score of 4 (in bed 100% of time).
- Uncorrectable coagulopathy, defined by INR>1.5 or platelets < 50 x 109/L.
- Clinically relevant gastric-outlet obstruction.
- Unable to complete sign informed consent.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	28-09-2021
Aantal proefpersonen:	21
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:	28-09-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 51255
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9757
CCMO	NL77539.029.21
OMON	NL-OMON51255

Resultaten