Endoscopic versus percutaneous biliary drainage in resectable hilar cholangiocarcinoma.

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This study is expected to identify less complications after percutaneous biliary drainage (PTBD) compared to endoscopic biliary drainage for resectable hilar cholangiocarcinoma.

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

Samenvatting

ID

NL-OMON28228

Bron
Nationaal Trial Register

Verkorte titel
DRAINAGE trial

Aandoening

bile duct tumor, jaundice, biliary drainage

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC)
Overige ondersteuning: KWF Kankerbestrijding (Dutch Cancer Society)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The combined incidence of severe complications related to EBD or PTBD between the initial

drainage after treatment allocation (i.e. the index drainage procedure) and the day of explorative laparotomy. A severe complication is defined as any complication related to biliary drainage, requiring an additional invasive or surgical intervention with subsequent prolonged hospital stay or death, or readmission for drainage related morbidity. When explorative laparotomy is cancelled a substitute endpoint will be used in analysis of the primary endpoint: (1) the total number of severe drainage-related complications between randomization and 1 week after biopsy in patients in whom the laparotomy is cancelled due to a diagnosis of distant metastatic disease, or (2) the total number of severe drainage-related
complications within 3 months after randomization in patients in whom the laparotomy is cancelled due to physical deterioration.

Toelichting onderzoek

Achtergrond van het onderzoek

Cholestasis is a significant risk factor in the treatment of patients with suspected hilar cholangiocarcinoma (HCCA) requiring major liver resection. Preoperative biliary drainage (PBD) attenuates the effects of cholestasis caused by the tumor, but there is controversy over the preferred technique of PBD, either via endoscopic biliary drainage (EBD) or using percutaneous transhepatic biliary drainage (PTBD).

The objective of this multi-center randomized controlled trial is to identify a difference in the incidence of drainage related complications between EBD and PTBD for preoperative biliary drainage of HCCA.

Inclusion criteria: Suspicion of resectable HCCA; serum bilirubine >50 µmol/l; inadequate biliary drainage of the future remnant liver.
Main exclusion criteria: Incomplete recovery from side effects of any prior stenting procedure; contraindication for major surgery.

Intervention: Patients will be allocated to undergo either EBD or PTBD.

Primary endpoint: The incidence of severe drainage related complications between the index drainage procedure and explorative laparotomy, defined as any complication requiring an additional invasive intervention or hospital admission.

Secondary endpoints: Technical success of stent insertion; the time from drainage until explorative laparotomy; number of rescheduled laparotomies for clinical reasons; length of hospital stay; number of invasive procedures; post-laparotomy morbidity and mortality; quality of life.

This study is expected to identify PTBD as the preferred technique of preoperative biliary drainage for resectable HCCA on the basis of fewer drainage related complications and consequential better quality of life. Furthermore postoperative mortality and morbidity is expected to decrease with PTBD compared to EBD.

Doel van het onderzoek

This study is expected to identify less complications after percutaneous biliary drainage (PTBD) compared to endoscopic biliary drainage for resectable hilar cholangiocarcinoma.

Onderzoeksopzet

Therapeutic success: control ultrasound of the liver 7 days after index drainage procedure and control bilirubin 7 and 14 days after index drainage procedure. Quality of life (EORTC QLQ-30, EORTC QLQ-BIL21, EQ-5D): date of inclusion (baseline), 7, 28 and 90 days after index drainage procedure.

Onderzoeksproduct en/of interventie

Crossover treatment:

Crossover treatment applies to patients who require a repeat or revision procedure, but in whom the allocated drainage modality is no longer technically feasible. Cross-over treatment from EBD to PTBD is protocol mandatory if EBD is unsuccessful to achieve technical success after 2 attempts.

Antibiotics: Standard antibiotic prophylaxes are administered at the start of each biliary drainage procedure, according to local protocol. Prophylactic antibiotic treatments must be similar for endoscopic and percutaneous biliary drainage procedures in each centre. Cholangitis is treated with intravenous
antibiotics, preferably 2 grams ceftriaxone i.v plus gentamicine 5mg/kg, during hospital admission.

Contactpersonen

Publiek

Academic Medical Center (AMC), Department of Surgery
P.O. Box 226600
Meibergdreef 9

T.M. Gulik, van
Amsterdam 1100 DD
The Netherlands
Tel +31 20 56 65570

Wetenschappelijk

Academic Medical Center (AMC), Department of Surgery
P.O. Box 226600
Meibergdreef 9

T.M. Gulik, van
Amsterdam 1100 DD
The Netherlands
Tel +31 20 56 65570

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Changed 17-jun-2014
- Diagnosis or suspicion of perihilar cholangiocarcinoma (pHCCA)

- No apparent signs of irresectability on CT-scan and/or MRI, and scheduled to undergo a “curative” liver resection (may need additional lymph node biopsies or a diagnostic laparoscopy to further determine resectability)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Incomplete recovery from side-effects of any prior stenting attempt

- Signs of active cholangitis, defined as Leukocytes ≥ 10 *109/L or antibiotic treatment for a suspicion of cholangitis within the past 5 days

- ECOG/WHO score ≥3

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	26-09-2013
Aantal proefpersonen:	106
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:	11-10-2013
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	NL4098
NTR-old	NTR4243
Ander register	KWF cancer foundation grant : 5925
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A