Hepatic arterial infusion pump chemotherapy in patients with unresectable intrahepatic cholangiocarcinoma

Gepubliceerd: 14-11-2019 Laatst bijgewerkt: 15-05-2024

Survival of patients treated with hepatic arterial infusion pump chemotherapy will be superior compared to patients treated with systemic chemotherapy only.

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

Samenvatting

ID

NL-OMON23810

Bron
NTR

Verkorte titel
PUMP II

Aandoening

Hepatic Arterial Infusion Pump (HAIP) chemotherapy, Unresectable intrahepatisch cholangiocarcinoma without presence of extrahepatic disease.

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center
Overige ondersteuning: Dutch Cancer Society

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1-year overall survival (OS)

Toelichting onderzoek

Achtergrond van het onderzoek

This is single-arm trial with the aim to assess the effectiveness and safety of HAIP chemotherapy and concurrent systemic chemotherapy in patient with unresectable ICC in the Netherlands.

Doel van het onderzoek

Survival of patients treated with hepatic arterial infusion pump chemotherapy will be superior compared to patients treated with systemic chemotherapy only.

Onderzoeksopzet

One year after inclusion of the last patient

Onderzoeksproduct en/of interventie

HAIP chemotherapy

Contactpersonen

Publiek

Erasmus MC
Stijn Franssen

010-7042125

Wetenschappelijk

Erasmus MC
Stijn Franssen

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age ≥ 18 years.

• ECOG performance status 0 or 1 (Appendix A).

• Histologically confirmed diagnosis of intrahepatic cholangiocarcinoma (ICC).

• Unresectable ICC confined to the liver (<70% of the liver involved) with or without limited regional lymph node disease (portal) at initial presentation, as confirmed by HPB surgeons. Regional lymph nodes will be allowed, provided it is potentially amenable to resection. Unresectability confirmed:
o Radiologically
o Or during surgical exploration in patients initially considered candidates for resection

• Patient is able to undergo a laparotomy or minimal-invasive surgery for pump placement.

• Positioning of a catheter for HAIP chemotherapy is technically feasible (see chapter 5) based on a CT with excellent arterial phase. The default site for the catheter insertion is the gastroduodenal artery (GDA). Accessory or aberrant hepatic arteries are no contraindication for catheter placement.

• Adequate bone marrow, liver and renal function as assessed by the following laboratory requirements to be conducted within 30 days prior to inclusion:
o Absolute neutrophil count (ANC) ≥ 1.5 x 109/L
o White blood cell count (WBC) ≥ 2.5 x 109/L
o Platelets ≥ 100 x 109/L
o Glomerular filtration rate (GFR) ≥ 60 ml/min
o Haemoglobin (HB) ≥ 5.5 mmol/L
o Total bilirubin ≤ 25 µmol/L

• Written informed consent must be given according to ICH/GCP, and national/local regulations.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Presence of extrahepatic disease at the time of first presentation. Patients with limited

(portal) lymph node disease, patients with small (≤ 1 cm) extrahepatic lesions that are too small to characterize are eligible.

• Second primary malignancy, except for adequately treated non-melanoma skin cancer, or other malignancy treated at least 3 years previously without evidence of recurrence or with a life expectancy longer than 5 years.

• Known DPYD deficiency.

• Prior hepatic radiation, ablation, or resection for cholangiocarcinoma.

• Life expectancy of less than 12 weeks.

• Clinical evidence of portal hypertension (ascites, gastroesophageal varices, or portal vein thrombosis). Surgically related ascites is allowed.

• (Partial) portal vein thrombosis.

• Pregnant or lactating women.

• History of psychiatric disability judged by the investigator to be clinically significant, precluding informed consent or interfering with compliance for HAIP chemotherapy.

• Serious concomitant systemic disorders that would compromise the safety of the patient or his/her ability to complete the study, at the discretion of the investigator.

• Organ allografts requiring immunosuppressive therapy.

• Serious, non-healing wound, ulcer, or bone fracture.

• Chronic treatment with corticosteroids (dose of ≥ 10 mg/day methylprednisolone equivalent excluding inhaled steroids).

• Serious infections (uncontrolled or requiring treatment).

• Participation in another interventional study for ICC with survival as outcome.

• Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial.

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:	01-12-2019
Aantal proefpersonen:	40
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:	14-11-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52590
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8234
CCMO	NL70452.078.19
OMON	NL-OMON52590

Resultaten