Adjuvant hepatic arterial infusion pump chemotherapy after resection of colorectal liver metastases.

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HAIP chemotherapy after resection of colorectal liver metastases (CRLM) will be feasible and safe.

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

Samenvatting

ID

NL-OMON27138

Bron
Nationaal Trial Register

Aandoening

Colorectal liver metastases, adjuvant, Hepatic Arterial Infusion Pump (HAIP) chemotherapy.

Colorectale levermetastasen, adjuvant, HAIP chemotherapie.

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: Erasmus Medical Center
Dutch Cancer Society

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome for feasibility is the percentage of successful administration of at least

one cycle of HAIP chemotherapy.

Toelichting onderzoek

Achtergrond van het onderzoek

This is a multicenter feasibility study to optimize the organization of HAIP chemotherapy in two Dutch centers (Erasmus MC Cancer Institute and Antoni van Leeuwenhoek)

Doel van het onderzoek

HAIP chemotherapy after resection of colorectal liver metastases (CRLM) will be feasible and safe.

Onderzoeksopzet

1 month after inclusion of the last patient

Onderzoeksproduct en/of interventie

Adjuvant HAIP chemotherapy

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age ≥ 18 years

• ECOG performance status 0 or 1

• Clinical Risk Score (CRS) of 0-5

• Histologically confirmed colorectal cancer (CRC)

• Radiologically confirmed and resectable CRLM.

• Positioning of a catheter for HAIP chemotherapy is technically feasible based on a CT with excellent arterial phase. The default site for the catheter insertion is the gastroduodenal artery (GDA).

• Adequate bone marrow, liver and renal function as assessed by the following laboratory requirements to be conducted within 15 days prior to inclusion:

o absolute neutrophil count ≥1.5 x 109/L

o platelets ≥100 x 109/L

o HB ≥ 5.5 mmol/L

o Total bilirubin ≤ 1.5 UNL

o ASAT ≤ 5 x UNL

o ALAT ≤ 5 x UNL

o alkaline phosphatase ≤ 5 x UNL

o (calculated) glomerular filtration rate >30 ml/min.

• 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 (including positive portal lymph nodes) at the time of liver resection or any time since CRC diagnosis. Patients with small (≤ 1 cm) extrahepatic lesions that are too small to characterize are eligible.

• Second primary malignancy except in situ carcinoma of the cervix, adequately treated non-melanoma skin cancer, or other malignancy treated at least 5 years previously without evidence of recurrence.

• Prior hepatic radiation or resection.

• CRLM requiring two-staged liver resections

• (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).

• Current or recent (within the 28 days prior to inclusion) treatment with another investigational drug or participation in another investigational study.

• 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:	02-11-2017
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:	18-12-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47208
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6739
NTR-old	NTR6917
CCMO	NL59706.078.17
OMON	NL-OMON47208

Resultaten

Samenvatting resultaten
N.A.