Adjuvant hepatic arterial infusion pump chemotherapy after resection of colorectal liver metastases in patients with a low clinical risk score – a randomized controlled trial

Gepubliceerd: 23-09-2018 Laatst bijgewerkt: 15-05-2024

Survival of patients treated with hepatic arterial infusion pump chemotherapy will be superior.

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

Samenvatting

ID

NL-OMON26427

Bron
Nationaal Trial Register

Verkorte titel
PUMP trial

Aandoening

Adjuvant treatment, Hepatic Arterial Infusion Pump (HAIP) chemotherapy, Resectable colorectal liver metastases

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is progression free survival (PFS).

Toelichting onderzoek

Achtergrond van het onderzoek

This is a multicenter randomized controlled trial comparing resection with adjuvant HAIP chemotherapy with resection alone in patient siwth resectable colorectal liver metastases.

Doel van het onderzoek

Survival of patients treated with hepatic arterial infusion pump chemotherapy will be superior.

Onderzoeksopzet

One year after inclusion of the last patient

Onderzoeksproduct en/of interventie

Adjuvant HAIP chemotherapy

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age ≥ 18 years.

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

• Histologically confirmed colorectal cancer (CRC).

• Radiologically confirmed CLM, amenable for local treatment (resection or open ablation). Criteria are outlined in section 5.1.1.

• Clinical Risk Score (CRS) of 0-2 (Appendix D). In patients with unknown nodal status (in case of synchronous resection of primary tumor and CLM), the nodal status is counted as zero.

• 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. The GDA should have at least one branch to the liver remnant; accessory or aberrant hepatic arteries should be ligated to allow for cross perfusion to the entire liver through intrahepatic shunts.

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

o absolute neutrophil count (ANC) ≥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 (GFR) >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 not clearly suspicious of metastases 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, resection, or ablation.

• CLM requiring two-staged resections.

• Liver-first resections.

• Postoperative radiation of not (adequately) treated CLM during surgery.

• (Partial) portal vein thrombosis.

• Known DPD-deficiency (heterozygous or homozygous)

• Pregnant women 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 CRLM 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:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	22-08-2018
Aantal proefpersonen:	230
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	23-09-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52926
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7277
NTR-old	NTR7493
CCMO	NL65956.078.18
OMON	NL-OMON52926

Resultaten