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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26427

Source
Nationaal Trial Register

Brief title
PUMP trial

Health condition

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

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Dutch Cancer Society

Intervention

Outcome measures

Primary outcome

The primary endpoint is progression free survival (PFS).

Secondary outcome

Secondary endpoints include OS, PFS in the liver, postoperative complications, adverse events, quality of life, and cost effectiveness. Also, the accuracy of CT angiography to detect extrahepatic perfusion will be evaluated. Next, we aim to identify predictive biomarkers for the efficacy of HAIP chemotherapy. Furthermore, the pharmacokinetic profile of intra-arterial administration of floxuridine will be established.

Study description

Background summary

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

Study objective

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

Study design

One year after inclusion of the last patient

Intervention

Adjuvant HAIP chemotherapy

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

• 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.

Exclusion criteria

• 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	22-08-2018
Enrollment:	230
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-09-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52926
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results