Intraperitoneal irinotecan with concomitant FOLFOX and bevacizumab for patients with unresectable colorectal peritoneal metastases - a phase II study

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This study has been transitioned to CTIS with ID 2024-517152-34-00 check the CTIS register for the current data. The primary objectives are to explore the overall survival for the addition of intraperitoneal irinotecan (75 mg) to palliative systemic...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Peritoneal and retroperitoneal conditions
Study type	Interventional

Summary

ID

NL-OMON56200

Source
ToetsingOnline

Brief title
INTERACT-II

Condition

- Peritoneal and retroperitoneal conditions
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Colorectal Cancer with metastasis in the peritoneum, Peritoneal carcinomatosis of colorectal origin

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Eigen bekosting van de betrokken afdelingen.

Intervention

Keyword: Colerectal cancer, Intraperitoneal chemotherapy, Peritoneal metastasis, Systemic chemotherapy

Outcome measures

Primary outcome

To determine the anti-tumor activity in patients treated with intraperitoneal irinotecan (75 mg) and concomitant mFOLFOX4, defined as (1) progression-free survival (calculated from the interval from the start of trial treatment until first evidence of intraperitoneal and/or systemic disease progression or last follow-up); (2) overall survival (calculated from (a) the interval from diagnosis of peritoneal metastases until death or last follow-up; (b) the interval from the first day of the first cycle until death or last follow-up).

Secondary outcome

The toxicity profile, patient reported outcomes, costs, tumor response during trial treatment, and the systemic and intraperitoneal pharmacokinetics of irinotecan and SN-38.

Study description

Background summary

The rationale of the current study is that the addition of intraperitoneal irinotecan (75 mg) to palliative systemic therapy is feasible and safe, and might result in an increased overall and progression free survival in patients

with unresectable colorectal peritoneal metastases.

Study objective

This study has been transitioned to CTIS with ID 2024-517152-34-00 check the CTIS register for the current data.

The primary objectives are to explore the overall survival for the addition of intraperitoneal irinotecan (75 mg) to palliative systemic therapy in patients with unresectable colorectal peritoneal metastases.
Secondary objectives are to assess the progression-free survival, toxicity profile, patient reported outcomes, costs, tumor response during trial treatment, and the systemic and intraperitoneal pharmacokinetics of irinotecan and SN-38.

Study design

This is a single-arm, open-label, phase II study that is performed in three Dutch tertiary referral centers for the surgical treatment of colorectal peritoneal metastases.

Intervention

The addition of intraperitoneal irinotecan (75 mg) to modified FOLFOX4 (mFOLFOX4) + bevacizumab

Study burden and risks

Trial participation involves several potential (small) risks. Firstly, during the diagnostic laparoscopy a peritoneal port is placed, which is associated with a small risk of surgical complications. Secondly given the addition of a cytostatic agent, the most important risk associated with trial participation involves an increased risk of locoregional or systemic toxicity.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Histologically confirmed colorectal cancer;
- Radiologically and clinically or pathologically confirmed unresectable colorectal peritoneal metastases (e.g. PCI >20, extensive small bowel involvement, unresectable disease due to anatomical location);
- WHO performance score of 0-1 with a life expectancy of >3 months;
- Aged 18 years or older;
- Written informed consent;

Exclusion criteria

- Presence of extensive systemic metastases that are deemed to be the dominant factor determining prognosis in terms of life expectancy and performance status [e.g. no imminent threat of impaired organ functioning due to the presence of systemic metastases]);
- Prior cytoreductive surgery;
- Prior palliative systemic therapy for colorectal cancer;
- Prior neo-adjuvant/adjuvant systemic therapy for colorectal cancer within the last 6 months;
- Homozygous UGT1A1*28 genotype;
- Homozygous dihydropyrimidine dehydrogenase (DPD) deficiency;
- Microsatellite instable (MSI) primary tumor;
- Any contra-indication for the planned chemotherapy (e.g. active infection, serious concomitant disease, severe allergy), as determined by the medical

oncologist;
- Inadequate organ functions, defined as an haemoglobin of <5 mmol/L, an absolute neutrophil count of <1.5 x 109/L, platelet count of <100 x 109/L, serum creatinine of >1.5 x ULN, creatinine clearance of <30 ml/min, Bilirubin > 2x ULN and liver transaminases of >5 x ULN;

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-12-2022
Enrollment:	85
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Irinotecan
Generic name:	Irinotecan
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	05-07-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	02-09-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-12-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EU-CTR	CTIS2024-517152-34-00
EudraCT	EUCTR2022-002134-14-NL
CCMO	NL81672.100.22