PIPAC for peritoneal metastases of colorectal cancer

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Repetitive ePIPAC-OX as a palliative monotherapy is a feasible, safe, tolerable, and potentially effective treatment for isolated unresectable colorectal peritoneal metastases, with low and predictable costs and a low systemic uptake of oxaliplatin...

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

Samenvatting

ID

NL-OMON21399

Bron
NTR

Verkorte titel
CRC-PIPAC

Aandoening

Colorectal Neoplasms; Cecal Neoplasms; Peritoneal Neoplasms; Peritoneal Metastases; Peritoneal Carcinomatosis; Colorectaal Carcinoom; Appendixcarcinoom; Peritoneale Metastasen; Peritonitis Carcinomatosa

Ondersteuning

Primaire sponsor: Catharina Hospital, Eindhoven, Netherlands
Overige ondersteuning: Catharina Hospital, Eindhoven, Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the number of patients with major toxicity, defined as grade ≥3 according to the Common Terminology Criteria for Adverse Events (CTCAE) v4.0, up to four weeks after the last ePIPAC-OX.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of study

Approximately a quarter of the patients who are diagnosed with colorectal cancer and metastases have their metastases in the peritoneum, the so called peritoneal metastases. The vast majority of these patients cannot be cured by surgery, frequently due to too many peritoneal metastases. These inoperable patients have a very short life expectancy. Nowadays, they are treated with chemotherapy through the veins. However, chemotherapy through the veins seems to be relatively ineffective against peritoneal metastases, probably because it does not reach the peritoneal metastases very well. Chemotherapy through the veins may also cause side effects that are sometimes severe. Recently, doctors developed PIPAC: a short laparoscopic operation during which chemotherapy is sprayed in the abdomen for 30 minutes every four to six weeks, directly against the peritoneal metastases. As a result, PIPAC may as effective against peritoneal metastases than chemotherapy through the veins, but it may cause less side effects because the chemotherapy stays in the abdomen. Although PIPAC indeed shows promising results in the first patients, little is still known about its safety, feasibility, tolerability, and efficacy.

Aim of study

To investigate whether PIPAC is a safe, feasible, tolerable, and potentially effective treatment for patients with inoperable peritoneal metastases of colorectal cancer.

Participants

Patients with inoperable peritoneal metastases of colorectal cancer without metastases elsewhere (e.g. liver, lung)

Treatment

Instead of chemotherapy through the veins, participants receive PIPAC every 6 weeks. PIPAC

is a laparoscopic operation under general anaesthesia. During PIPAC, chemotherapy is sprayed in the abdomen for about 30 minutes. After PIPAC, patients stay in the hospital for one night. Four weeks after each PIPAC, patients visit the hospital for a scan and to evaluate whether PIPAC can be continued. PIPAC is continued until (1) the cancer grows, (2) PIPAC causes unacceptable side effects, or (3) PIPAC is technically not possible to perform. In case no further PIPAC is performed, restarting chemotherapy through the veins is discussed with the patient.

Potential risks for participants

PIPAC may cause side-effects. The most frequent potential side-effects are pain, nausea, fever, wound infection, diarrhea, obstipation, and minor damages to the kidney, liver, and bone marrow. These side-effects are mostly very mild. Moreover, the risk of side-effects of PIPAC is thought to be lower than the risk of side-effects of chemotherapy through the veins. Severe side-effects of PIPAC are extremely rare. The most important are a bowel perforation or a bleeding during PIPAC. So far, these severe side-effects have not been observed during PIPAC in patients with peritoneal metastases of colorectal cancer.

Potential benefits for participants

PIPAC may potentially be similarly effective against peritoneal metastases than chemotherapy through the veins, with a potential lower risk of side-effects. However, these potential benefits remain uncertain. The cancer may deteriorate at any moment during treatment with PIPAC.

Hypothesis of study

The investigators expect that PIPAC is a safe, feasible, tolerable, and potentially effective treatment for patients with peritoneal metastases of colorectal cancer.

Doel van het onderzoek

Repetitive ePIPAC-OX as a palliative monotherapy is a feasible, safe, tolerable, and potentially effective treatment for isolated unresectable colorectal peritoneal metastases, with low and predictable costs and a low systemic uptake of oxaliplatin.

Onderzoeksopzet

See sections 'Primary outcome(s)' and 'secondary outcome(s)' above

Onderzoeksproduct en/of interventie

Instead of standard palliative treatment, enrolled patients receive laparoscopy-controlled ePIPAC-OX (92 mg/m2 body-surface area [BSA]) with intravenous leucovorin (20 mg/m2 BSA) and bolus 5-fluorouracil (400 mg/m2 BSA) every six weeks. Four weeks after each procedure, patients undergo clinical, radiological, and biochemical evaluation. ePIPAC-OX is repeated until clinical, radiological, or macroscopic disease progression, after which standard palliative treatment is (re)considered.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Eligible patients are adults who have:

 a World Health Organisation (WHO) performance status of ≤1 and life expectancy >3 months;

 histological or cytological proof of PM of a colorectal or appendiceal carcinoma;

 unresectable disease determined by abdominal computed tomography (CT) and a diagnostic laparoscopy or laparotomy;

 adequate organ functions (haemoglobin ≥5.0 mmol/L, neutrophils ≥1.5 x 109/L, platelets ≥100 x 109/L, serum creatinine <1.5 x ULN, creatinine clearance ≥30 ml/min, and liver transaminsases <5 x ULN);

 no symptoms of gastrointestinal obstruction;

 no radiological evidence of systemic metastases;

 no contraindications for oxaliplatin or 5-fluorouracil/leucovorin;

 no contraindications for a laparoscopy;

 no previous PIPAC-procedures;

 written informed consent.

Importantly, enrolment is allowed for patients with an unresected primary tumour (if asymptomatic) and for patients in various lines of palliative treatment, including patients who refuse, have not had, or do not qualify for first-line palliative systemic therapy. All potentially eligible patients are discussed in a multidisplinary team. Enrolled patients need to be informed about the potential consequences of postponing or discontinuing standard palliative treatment by a medical oncologist prior to enrolment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

See inclusion criteria

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2017
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	01-08-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6426
NTR-old	NTR6603
Ander register	EudraCT (2017-000927-29), Dutch competent authority (NL60405.100.17) : ClinicalTrials.gov (NCT03246321)
ISRCTN	ISRCTN89947480

Resultaten