Prevention of recurrent disease by additional chemotherapy in patients with detectable circulating tumor DNA in the blood after surgery for stage II (lymph nodes unaffected) colon cancer.

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Adjuvant chemotherapy in stage II CC patients with detectable postoperative ctDNA will lead to a 30% lower risk of disease recurrence within two years compared to standard treatment (regular follow-up).

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25151

Bron
Nationaal Trial Register

Aandoening

Stage II colon cancer, adjuvant chemotherapy, circulating tumor DNA

Ondersteuning

Primaire sponsor: Dutch Colorectal Cancer Group (DCCG)
Overige ondersteuning: Grant StandUpToCancer (SU2C)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Recurrence Rate (RR) 2 years after surgery

Toelichting onderzoek

Achtergrond van het onderzoek

Background and rationale

Patients with stage II CC have a good chance of survival, however, 15-20% of patients with stage II CC experience recurrence of disease. Only patients with clinicopathological high-risk factors (T4 tumor as most important factor) are offered ACT.

In stage II CC solid support and consensus is lacking regarding effectiveness of ACT.

Recently, ctDNA was shown to have a strong association with disease recurrence in stage II CC. In >80% of patients with detectable ctDNA after surgery disease recurrence occurred within 2 years. Whether ACT can reduce the RR in patients with detectable ctDNA is not known, and therefore we propose a cohort multiple Randomized Controlled Trial (cmRCT) to evaluate effectiveness of ACT in stage II CC patients with detectable ctDNA after surgery.

Methods
Stage II CC patients, included in the Prospective Dutch CRC cohort (PLCRC) and not considered for ACT by the treating physician, will be randomized 1:1 according to the cmRCT design. In patients randomized to the intervention arm, ctDNA results will be determined immediately after surgery. Patients with detectable ctDNA will be offered ACT (CAPOX/FOLFOX). In the control group, ctDNA will be analyzed batch-wise at the end of the trial and results will not be used in patient care. Patients in this arm will not receive ACT according to standard clinical care.

Doel van het onderzoek

Adjuvant chemotherapy in stage II CC patients with detectable postoperative ctDNA will lead to a 30% lower risk of disease recurrence within two years compared to standard treatment (regular follow-up).

Onderzoeksopzet

- Enrollment in PLCRC and observational PLCRC-MEDOCC study before surgery

Obtaining IC, blood withdrawal 1-3 weeks after surgery, ctDNA analysis

Onderzoeksproduct en/of interventie

Adjuvant chemotherapy 6 months CAPOX or FOLFOX

Contactpersonen

Publiek

Kamer Q04.4.21, UMC Utrecht

K.L. van Rooijen
Heidelberglaan 100

Utrecht 3584 CX
The Netherlands
06-46919566

Wetenschappelijk

Kamer Q04.4.21, UMC Utrecht

K.L. van Rooijen
Heidelberglaan 100

Utrecht 3584 CX
The Netherlands
06-46919566

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Inclusion in PLCRC cohort study, informed consent for repeated blood withdrawals and invitation for future researh

2. Inclusion in observational substudy PLCRC-MEDOCC

3. Histological confirmation of stage II colon cancer

4. Fit for combination chemotherapy

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Incomplete resection (R1 or R2 resection)

2. Other malignancy in previous 5 years (except for skin cancer other than melanoma and carcinoma in situ)

3. Indication for ACT according to treating physician

4. Contra-indication for systemic treatment with fluoropyrimidines and oxaliplatin

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2018
Aantal proefpersonen:	1320
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL6281
NTR-old	NTR6455
Ander register	: None

Resultaten