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.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25151

Source
Nationaal Trial Register

Health condition

Stage II colon cancer, adjuvant chemotherapy, circulating tumor DNA

Sponsors and support

Primary sponsor: Dutch Colorectal Cancer Group (DCCG)
Source(s) of monetary or material Support: Grant StandUpToCancer (SU2C)

Intervention

Outcome measures

Primary outcome

Recurrence Rate (RR) 2 years after surgery

Secondary outcome

- 5-year Recurrence Rate

- 5 and 7-year overall survival (OS)

- quality of life (QoL)

- cost-effectiveness analysis

Study description

Background summary

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.

Study objective

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).

Study design

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

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

Intervention

Adjuvant chemotherapy 6 months CAPOX or FOLFOX

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2018
Enrollment:	1320
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL6281
NTR-old	NTR6455
Other	: None

Study results