The PLCRC-PROTECT+ study: PLCRC cohort: lean body mass and treatment toxicities in adjuvant chemotherapy-receiving colon cancer patients

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The primary objective of this study is to investigate the association between changes of lean body mass and overall grade 2-4 toxicity during adjuvant chemotherapy in colon (or rectal) cancer patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON47422

Source
ToetsingOnline

Brief title
The PLCRC-PROTECT+ study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
adenocarcinoma, colon cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Subsidie van de provincie Utrecht,Universiteit Utrecht, UMCU, en Nutricia Research

Intervention

Keyword: Colon cancer, Lean body mass, Physical activity, Toxicity

Outcome measures

Primary outcome

The main study parameter of this observational study is overall grade 2-4 treatment-related toxicity. All clinical parameters and data on colon cancer outcome will be gathered from PLCRC (data management performed by the Netherlands Cancer Registry (NCR)). Grade 2 toxicity will not be recorded in the NKR+ database. In order to be able to obtain data on the occurrence of grade 2-4 toxicity during adjuvant chemotherapy, the treating medical oncologist has to document the toxicities very accurately. Subsequently, the study team of PLCRC-PROTECT+ have to gather the grade 2-4 toxicity data from the electronic patient files.

Furthermore, we will make use of *Electronic Patient Reported Outcomes* (ePRO) to measure treatment toxicities. We send out short digital questionnaires, one week after administration of every adjuvant chemotherapy cycle.

Secondary outcome

Secondary parameters of this observational study are: specific subgroups of overall grade 2-4 treatment-related toxicity, total chemotherapy adherence and adherence at each chemotherapy cycle, dose reductions with reason, drug delay or premature ending of chemotherapy. Furthermore, PIFA levels, treatment

response (disease progression and recurrence) and quality of life data, during

and after chemotherapy will be secondary parameters.

All clinical parameters (except for toxicity data) and data on colon cancer

outcome will be gathered from the PLCRC observational cohort study and the NCR.

Study description

Background summary

Colon cancer is one of the most common types of cancer and only 62% of the patient survive more than 5 years [IKNL, 2016]. In the adjuvant setting, chemotherapy completion rates are not optimal and dose reductions are often required because of treatment toxicities. Evidence is accumulating that lean body mass (LBM), which can be influenced by dietary intake and physical activity, is related to treatment toxicity, but precise associations are yet unknown. To date, little is known about the role of nutrition and lifestyle on LBM in colon cancer patients, and how this will develop during adjuvant chemotherapy regimens.
Since no studies have been performed so far, this prospective study in adjuvant chemotherapy-receiving colon cancer patients is warranted to investigate if changes in LBM occur, which factors can contribute to changes in LBM and how this affects treatment toxicities, recurrence and survival.

Study objective

The primary objective of this study is to investigate the association between changes of lean body mass and overall grade 2-4 toxicity during adjuvant chemotherapy in colon (or rectal) cancer patients.

Study design

The PLCRC-PROTECT+ study is an observational study.

Study burden and risks

By participating in this observational study, patients will contribute to scientific research on the impact of modifiable lifestyle factors and LBM on colon cancer outcome. This study will provide insight into the evolution of LBM throughout adjuvant chemotherapy and how modifiable risk factors can contribute. The aim is to find factors that are associated with overall grade (and subgroups of) 2-4 toxicities during adjuvant chemotherapy in colon cancer

patients.
For the PLCRC-PROTECT+ study, three blood samples will be taken in a period of approximately 10 months. For patients included and treated in the UMCU a total of six blood samples will be drawn. This amount of samples is compatible with the obtained IC in the PLCRC cohort, where we ask the patient for IC to draw blood samples on multiple time points with a maximum of 10 tubes of 10ml per patient per year at non-predetermined moments during routine blood withdrawals. For all these study-related blood samples the patient will already be in the hospital and the patient does not need an extra venepuncture. Depending on the hospital*s daily practice, the patient will get one or two extra CT-scans for study purposes. Every patient will at least get one extra CT-scan during adjuvant chemotherapy. Furthermore, depending on the hospital*s policy whether to use ultrasound or CT for follow-up imaging, we either use the follow-up CT-scan or an extra CT-scan will be made for study purposes after chemotherapy, during the first follow-up only. After this study-related follow-up CT-scan, the hospital will continue to use its normal follow-up policy.
To measure treatment-toxicities accurately, we will make use of *Electronic Patient Reported Outcomes* (ePRO). We send out a short digital questionnaire, two weeks after administration of every adjuvant chemotherapy cycle. Every patient can receive a maximum of eight cycles of chemotherapy, so the maximum time-investment will be (eight times five minutes) 40 minutes. Since grade 2-4 treatment toxicity is the primary outcome of the study, it is essential that we take into account all scientific recommendations for accurately measuring toxicity data, and therefore use patient-reported data collection.

The only risk associated by participating in this observational study is related to the radiation from one to two extra CT-scans added to the clinical routine CT. The radiation committee of the UMCU concluded that the use of ionising radiation in the context of the study is warranted. A letter of approval is separately added to this protocol. Other measurements do not induce extra health risks in this study.

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

- Age >=18.
- Histological confirmed colon cancer, (high risk stage II or stage III*), or rectal cancer.
- Colon or rectal (rectosigmoid, treated as colon) cancer patients who will receive adjuvant chemotherapy.
- Signed informed consent for participation in the PLCRC study (including informed consent for the collection of blood samples, invitation to future research and filling in questionnaires).
- Signed informed consent for the PLCRC-PROTECT study.
- Signed informed consent for the PLCRC-PROTECT+ study.

Exclusion criteria

- Non Dutch speaking patients.
- Mentally incompetent patients.
- Patients that receive(d) neo-adjuvant chemotherapy
- Patients who received one or more cycles of systemic therapy in the past 6 months.
- Pregnant or lactating women.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-01-2017
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	12-10-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-04-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-10-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-11-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	07-02-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	06-03-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-03-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL57839.041.16