Chemotherapy-induced peripheral neuropathy; its impact on colorectal cancer patients' lives

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

Summary

ID

NL-OMON43710

Source
ToetsingOnline

Brief title
The PROCORE study

Condition

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

Synonym
Colorectal cancer; colorectal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Integraal Kankercentrum Nederland, locatie Eindhoven
Source(s) of monetary or material Support: KWF kankerbestrijding en European

Foundation for the Study of Diabetes (EFSD)

Intervention

Keyword: -chemotherapy, -Chemotherapy-induced peripheral neuropathy, -Colorectal cancer, -patient-reported outcomes

Outcome measures

Primary outcome

Neuropathy, health-related quality of life, disease-specific complaints,

depression, fatigue, sleep problems, personality, comorbidity, physical

activity, health care utilisation, health supplement use, employment, genetic

and biological markers including pro-and anti-inflammatory cytokines (IL-1β,

IL-6, TNF-α, IL-RN, and IL-10) genes.

Secondary outcome

not applicable

Study description

Background summary

Due to the increasing prevalence of cancer, more patients are living with the side-effects of cancer and its treatment. Especially the development of chemotherapy-induced peripheral neuropathy (CIPN) is a major concern. CIPN is a condition featuring pain, numbness, tingling, and sensitivity to cold in the hands and feet which sometimes progresses to the arms and legs. Its prevalence is expected to increase since the indications for chemotherapy are broadened and new chemotherapeutic agents with CIPN side-effects are in use. Although the number of patients at risk for CIPN is likely to increase, its influence on patient-reported outcomes, health care utilisation, physical activity, and employment are often unknown as is the role of personality on CIPN experience.

Study objective

We aim to gain insight into the incidence and severity of CIPN and its influence on patient-reported outcomes (i.e. health related quality of life

(HRQoL), disease-specific complaints, depression, fatigue, sleep problems) among a prospective population-based sample of colorectal cancer (CRC) patients. Furthermore, we will study the role of personality on CIPN experience and we will investigate the influence of CIPN on health care utilisation, physical activity, and employment. Finally, we will investigate the role of genetic/biological markers of inflammation on neuropathy, HRQOL and pain.

Study design

We plan to perform a prospective population-based study in which we include CRC patients before the start of treatment and follow them until 2 years after treatment. Patients from the hospitals in the Eindhoven Cancer Registry area will be asked to fill out questionnaires on CIPN, HRQoL, depression, fatigue, sleep problems, personality, health care utilisation, physical activity, health supplements use, and employment at 4 points in time (before surgery, within a month after surgery (e.g. before chemotherapy), within a month after chemotherapy (e.g. one year after diagnosis), and 2 years after diagnosis. In Máxima Medisch Centrum, we will ask patients who underwent a curative surgery to fill in a short questionnaire on HRQoL at an extra point in time (i.e., 3 months after surgery). Clinical data like disease stage, cumulative dose of chemotherapy and dose reductions will be extracted from patients* medical records and the Eindhoven Cancer Registry. Also, patients will be asked to donate a blood sample 3 times (2X10 ml, 10 minutes) in order to examine the association between HRQOL, pain, genetic and biological markers of inflammation. The blood draws will take place at the hospital.

Study burden and risks

In three of the four hospitals, patients will be asked to fill in a questionnaire (+/-40 minutes a questionnaire) at 4 points in time. In Máxima Medisch Centrum, patients who underwent a curative surgery will be asked to fill in a short questionnaire (+/-10 minutes) at an extra point in time (i.e., three months after surgery). Also, patients from all four hospitals will be asked to donate blood on three occasions. The blood draws will take place at the hospitals.

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

- Diagnosed with colorectal cancer
- 18 years or older

Exclusion criteria

- Patients with cognitive impairment will not be included because of expected difficulties in completing these questionnaires without assistance.
- Patients who are not able to read or write Dutch will be excluded, as they are not able to complete a Dutch questionnaire.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2016
Enrollment:	800
Type:	Actual

Ethics review

Approved WMO Date:	01-06-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-06-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Not approved Date:	01-03-2022
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
CCMO	NL51119.060.14

Study results

Results posted: 24-12-2021

First publication
24-12-2021