Diagnostic yield of screening colonoscopy in testicular cancer survivors treated with platinum-based chemotherapy

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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-OMON48363

Source
ToetsingOnline

Brief title
CATCHER

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms benign

Synonym
(sessile) polyps, adenomas, neoplasia

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Colonoscopy, Platinum-based chemotherapy, Testicular cancer, Therapy-induced neoplasia

Outcome measures

Primary outcome

To determine the diagnostic yield of advanced colorectal neoplasia by screening colonoscopy in TC survivors treated with platinum-based chemotherapy

Secondary outcome

- To determine whether the molecular profile of colorectal neoplasia in TC survivors treated with platinum-based chemotherapy differs from sporadic colorectal neoplasia

- To examine whether we can detect platinum in plasma and if so to examine whether platinum levels are associated with the outcome of advanced colorectal lesions and cumulative cisplatin dose

- To develop colonoscopy surveillance screening recommendations for TC survivors treated with platinum-based chemotherapy

- To evaluate the burden of screening colonoscopy in TC survivors treated with platinum-based chemotherapy

- To evaluate the cost-effectiveness of colonoscopy in TC survivors treated with platinum-based chemotherapy

- To evaluate the sensitivity and specificity of stool tests for detecting advanced colorectal neoplasia in TC survivors treated with platinum-based

chemotherapy

Study description

Background summary

Testicular cancer (TC) survivors have an increased risk of various second primary malignancies. A recent cohort study showed that platinum-based chemotherapy was associated with increased risk of colorectal cancer (CRC) in a dose dependent manner (hazard ratio (HR) 3.85 for platinum-containing chemotherapy versus no platinum-containing chemotherapy, 95% confidence interval 1.67-8.92). An increased risk of secondary gastrointestinal malignancies also has been previously described in childhood cancer survivors treated with platinum-based chemotherapy with a relative risk of 7.6. Recently, colonoscopy surveillance has also been recommended in Hodgkin lymphoma survivors treated with abdominal radiotherapy and/or procarbazine. Currently, it is unknown whether CRC that develop in TC survivors exposed to cisplatin are histopathologically or molecularly different from sporadic CRC. If present, such differences might be related to the previous cisplatin treatment.The aim of this multicentre prospective study is to assess the diagnostic yield of colonoscopy surveillance in TC survivors treated with platinum-based chemotherapy, mainly cisplatin. We will evaluate whether these patients will benefit from surveillance. We will compare screening yields with that a control group of the NordICC study including average individuals who underwent a first screening colonoscopy. Also the molecular profile of advanced neoplasia will be assessed to detect possible differences with sporadic neoplasia, which will hopefully contribute to more personalized CRC treatment. Additionally, we will determine the level of platinum in both the plasma and colorectal tissue to evaluate a possible correlation with the development of advanced neoplastic colorectal lesions and/or CRC. Furthermore, we will evaluate the burden and cost-effectiveness of colonoscopy and assess the effectiveness of stool tests for CRC screening in TC survivors compared to standard colonoscopy.

Study objective

Primary objective of this multicenter study is to assess the diagnostic yield of colonoscopy surveillance in testicular cancer (TC) survivors treated with platinum-based chemotherapy (cisplatin). Furthermore, we will evaluate the molecular profile of advanced colorectal neoplasia, effectiveness of stool tests, platinum in plasma, burden and cost-effectiveness of colonoscopy.

Study design

A prospectively cross-sectional screening study in multicenter setting.

Study burden and risks

Participation of patients in this study can be considered as standard care due to the fact that these patients should be offered colonoscopy surveillance as they can be considered a high-risk population for developing CRC. Patients will visit the hospital at least two times (once for an intake and once to undergo a colonoscopy). Depending on the outcome of the colonoscopy patients will receive a telephone consultation or an appointment at the outpatient clinic. Participants are asked for one blood sample when they visit the hospital for either intake or colonoscopy (6 ml EDTA containing tube). Patients will be asked to fill out two questionnaires before and after colonoscopy and to provide a stool sample for fecal testing before the start of the bowel preparation. Participation in this study provides a first screening colonoscopy with the potential to detect and resect colorectal neoplasia. Six to eigth additional biopsies of normal colorectal tissue will be taken with minimal additional risk.

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

- Diagnosis of TC before age of 50 years
- Treatment of primary TC consisting at least three cycles of platinum-based chemotherapy consisting of cisplatin
- At least 8 years after initial treatment
- At least 35 years of age and not older than 75 years
- Detection and potential treatment of advanced colorectal neoplasia is considered useful

Exclusion criteria

- A history of a proctocolectomy
- Colonoscopy surveillance for other indications (including hereditary CRC syndrome, familial CRC syndrome, inflammatory bowel disease, history of colorectal adenoma or CRC). Result of the prior colonoscopy will be put in the database and used for additional analyses
- Having received a colonoscopy in the past three years (however the result of the prior colonoscopy will be put in the database and used for additional analyses)
- Currently receiving cytotoxic treatment or radiotherapy for malignant disease
- Coagulopathy (prothrombin time <50% of control; partial tromboplastin time >50 seconds) or anticoagulants (fenprocoumon, acenocoumarol, platelet aggregation inhibitors or new oral anticoagulants) that cannot be stopped or savely bridged
- Comorbidity leading to an impaired physical performance (World health organization (WHO) performance status 3-4) or mental retardation
- Limited Dutch language skills
- No informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2021
Enrollment:	234
Type:	Actual

Ethics review

Approved WMO Date:	11-09-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	04-12-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-12-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-02-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-04-2020
Application type:	Amendment
Review commission:	METC NedMec

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	NL68513.031.19