Diagnostic yield of screening colonoscopy in Hodgkin lymphoma survivors

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

Summary

ID

NL-OMON44361

Source
ToetsingOnline

Brief title
DICHOS

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms benign

Synonym
adenomas, neoplasia, polyps

Research involving
Human

Sponsors and support

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

zullen worden gefinancierd door het VUmc ,MLDS subsidie

Intervention

Keyword: Colonoscopy, Hodgkin lymphoma, therapy-induced neoplasia

Outcome measures

Primary outcome

- Diagnostic yield of advanced colorectal neoplasia detected by a colonoscopy

Secondary outcome

- Molecular characteristics of advanced colorectal neoplasia

- The relation of neoplasia characteristics to radiotherapy and / or

chemotherapy

- The cost-effectiveness of colonoscopy screening

- The burden of colonoscopy screening

- Performance of fecal immunochemical test and molecular stool test

- The development of CRC surveillance guidelines for HL survivors

Study description

Background summary

Second primary malignancies are a major cause of morbidity and mortality in Hodgkin lymphoma (HL) survivors. A recent retrospective analysis showed an increased incidence of colorectal cancer (CRC) in long-term survivors of HL compared with the general population (standardized incidence ratio (SIR) of 2.7 (95% confidence interval (CI) 2.0-3.6). HL survivors who were treated with high dose (>4.2 g/m2) procarbazine or infradiaphragmatic radiotherapy in combination with chemotherapy have an even higher risk (SIR 4.7 (95% CI 2.7-7.6) and 5.6 (95% CI 3.5-8.4), resp.).
Radiotherapy- or chemotherapy-associated CRC may be a distinct subgroup with a different etiology and prognosis and may require a different clinical approach. Because of the high CRC risk, HL survivors should be offered colonoscopy screening, which reduces CRC incidence and mortality. However, the diagnostic

yield, cost-effectiveness and burden of colonoscopy in HL survivors have not been assessed. The molecular profile of radiotherapy- or chemotherapy-associated colorectal neoplasia is also unknown.

Study objective

The first objective is to assess the value of colonoscopy screening in HL survivors. The second objectives are to evaluate the neoplasia characteristics and its relation to radiotherapy and chemotherapy, in order to improve the understanding of the carcinogenesis of colorectal neoplasia after the exposure to radiotherapy and / or chemotherapy, to evaluate the cost-effectiveness and to evaluate the burden of colonoscopy.
Finally, the effectiveness of a stool test for screening will be evaluated using the colonoscopy as a reference value.

Study design

A prospective cohort study in a multicenter setting.

Study burden and risks

The high risk of CRC is an indication for colonoscopy screening in HL survivors. Participation in the study includes the minimal additional risk of six to eight normal tissue biopsies. Patients will be asked to fill out two questionnaires and to provide one stool sample for a fecal immunochemical test and a molecular test.
Participation in this study provides no individual benefit for the patient.

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

• HL diagnosis at the age of 16-50 years
• Treatment for HL between 1965 and 2007
• Treatment of primary or recurrent HL consisting of
o infradiaphragmatic radiotherapy (any field(s)) and chemotherapy (any regimen)
and/or
o infradiaphragmatic radiotherapy consisting of at least para-aortal and iliac fields
and/or
o chemotherapy containing a cumulative procarbazine dose of >=2.8 g/m2
(e.g. >=2 MOPP, >=4 BEACOPP or >=4 MOPP/ABV courses)
• Survival of at least 8 years after the first treatment that included infradiaphragmatic radiotherapy and chemotherapy or procarbazine-containing chemotherapy
• Age of 25 years or older
• Life expectancy of five years or more

Exclusion criteria

• Proctocolectomy
• Colonoscopy surveillance for other indications (including hereditary CRC syndrome, familial CRC syndrome, inflammatory bowel disease, history of colorectal adenoma or CRC)
• Colonoscopy in the past five years
• On-going cytotoxic treatment or radiotherapy for malignant disease
• Coagulopathy (prothrombin time < 50% of control; partial thromboplastin time > 50 seconds) or anticoagulants (marcoumar, acenocoumarol or new oral anticoagulants) that cannot be stopped
• Comorbidity leading to an impaired physical performance (World health organization (WHO) performance status 3-4) or mental retardation
• 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:	Recruiting
Start date (anticipated):	29-01-2015
Enrollment:	259
Type:	Actual

Ethics review

Approved WMO Date:	10-10-2014
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	30-03-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL48096.031.14