The value of a colonoscopy in patients treated for Hodgkin lymphoma.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27361

Source
Nationaal Trial Register

Brief title
DICHOS

Health condition

late effects of Hodgkin lymphoma treatment
colorectal neoplasia

Sponsors and support

Primary sponsor: NKI-AVL
Source(s) of monetary or material Support: NKI-AVL
MLDS

Intervention

Outcome measures

Primary outcome

The diagnostic yield of advanced colorectal neoplasia detection by a first screening colonoscopy. Advanced colorectal neoplasia is defined as an adenoma with high grade dysplasia, >25% villous component or more than 10 mm diameter or CRC.

Secondary outcome

- the molecular profile of colorectal neoplasia in HL survivors
- the relation of colorectal neoplasia characteristics (anatomic distribution, histology, molecular changes) with radiotherapy and chemotherapy
- the cost-effectiveness of screening colonoscopy in HL survivors
- the burden of screening colonoscopy in HL survivors
- the performance of the fecal immunochemical test (FIT) and a molecular stool test using the colonoscopy as a reference value
- the development colonoscopy surveillance recommendations for HL survivors

Study description

Background summary

Hodgkin lymphoma survivors have an increased risk of developing colorectal cancer. Currently, there is no surveillance program for colorectal cancer in Hodgkin lymphoma survivors and the potential value of different surveillance methods in this population is unknown.
The first objective of this study 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 objective

Because of the high colorectal cancer (CRC) risk, Hodgkin lymphoma (HL) survivors should be offered colonoscopy screening, which has the potential to reduce 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 design

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Intervention

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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Eligibility criteria

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 infradiaphragmatic radiotherapy and chemotherapy (any regimen) or 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

Inclusion NEW: 4-apr-2016
-HL diagnosis at the age of 16-50 years
-Treatment for HL between 1965 and 2007
-Treatment of primary or recurrent HL consisting of infradiaphragmatic radiotherapy (any fields) and chemotherapy (any regimen) and/or infradiaphragmatic radiotherapy consisting of at least para-aortic and iliac fields and/or 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 this treatment

-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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2015
Enrollment:	259
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	10-12-2014
Application type:	First submission

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	NL4837
NTR-old	NTR4961
CCMO	NL.48096.031.14

Study results

Summary results

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