

The effect of treatment on fertility parameters in children with Hodgkins' Lymphoma

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To respectively evaluate the fertility parameters before and after treatment for pediatric HL in the Netherlands according to the COG protocols for low risk, intermediate risk and high risk, to test the hypothesis that these protocols will not harm...

Ethical review	Approved WMO
Status	Pending
Health condition type	Lymphomas Hodgkin's disease
Study type	Observational invasive

Summary

ID

NL-OMON30699

Source

ToetsingOnline

Brief title

Treatment effect on fertility in children with HD

Condition

- Lymphomas Hodgkin's disease

Synonym

lymphnode cancer, Morbus Hodgkin

Research involving

Human

Sponsors and support

Primary sponsor: Stichting Kinderoncologie Nederland

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: children, fertility, Hodgkins'Disease, treatment

Outcome measures

Primary outcome

This study will give insight in the direct and late effects of the used chemotherapy in pediatric patients with HL using the most novel fertility markers. If these chemotherapeutic agents do not show gonadal damage, it will support future studies with these agents. If certain regimens indicate direct or late gonadal toxicity, this will urge early counseling in this cohort.

Secondary outcome

not applicable

Study description

Background summary

In a retrospective study, in a cohort of 86 adults treated for pediatric HL with chemotherapy only in Amsterdam and Rotterdam, after a median follow-up of 25 years fertility parameters were investigated. The results showed in this long term follow-up cohort, that Inhibine B was the best predictor for infertility in men. AMH was found to be decreased in women who received MOPP even in patients with normal FSH and in contrast to women who received EBVD only.

Study objective

To respectively evaluate the fertility parameters before and after treatment for pediatric HL in the Netherlands according to the COG protocols for low risk, intermediate risk and high risk, to test the hypothesis that these protocols will not harm gonadal function.

Study design

Pediatric patients treated in the Netherlands according to a COG Hodgkin

protocol, boys 8 yrs and > 8 yrs at diagnosis, girls 9 yrs and > 9 yrs at diagnosis.

At 3 time points: 1. before start treatment, 2. after treatment, 3. three years after treatment (or if pts have not reached the age of 18 at the age of 18 yrs)

At time point 3 also semen analysis.

Study burden and risks

Bloodsampling can be painful with possible bruising, infection or bleeding. However, bloodsampling can be performed during routine blood sampling.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

Pediatric patients treated in the Netherlands according to the COG Hodgkin Disease protocols, boys > 8 years, girls > 9 years

Exclusion criteria

Pediatric patients not treated on a COG Hodgkins'Disease protocol, boys < 8 yrs, girls < 9 yrs

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-06-2006

Enrollment: 75

Type: Anticipated

Medical products/devices used

Registration: No

Ethics review

Approved WMO

Date: 31-07-2007

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL12889.042.06