# 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...

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| **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 inthe direct and late effects of the used

chemotherapy in pediatrics 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 counceling 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 emen analysis.

**Study burden and risks**

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

## Contacts

**Public**
Stichting Kinderoncologie Nederland

Leyweg 299
2545CJ Den Haag
Nederland
**Scientific**
Stichting Kinderoncologie Nederland

Leyweg 299
2545CJ Den Haag
Nederland

## 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

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-06-2006 |
| Enrollment: | 75 |
| Type: | Anticipated |

### Medical products/devices used

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|---|---|
| Registration: | No |

## Ethics review

Approved WMO

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| 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 |