Monitoring of TARC and MDC in blood as tool to evaluate disease activity in patients with Hodgkin Disease

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The aim of this project is a prospective study of blood samples of HL patients to determine the value sensitivity and specificity of increase TARC an MDC serum levels for the early detection of a relapse.

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

Summary

ID

NL-OMON30450

Source
ToetsingOnline

Brief title
Monitoring TARC and MDC in Hodgkin Disease

Condition

- Lymphomas Hodgkin's disease

Synonym
lymphnode cancer, Morbus Hodgkin

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: TARC MDC Hodgkin Disease

Outcome measures

Primary outcome

* Including children with Morbus Hodgkin in the Netherlands in this study will give a larger power to this study and does mean sooner sufficient patient accrual to achieve a reliable result concerning the value of TARC monitoring to determine the disease activity.

* In adult patients is has been proved that the TARC level after treatment has a prognostic value. By including children with Morbus Hodgkin we'll be able to determine if this is also the case with children.

* By collecting blood during treatment we possibly can get a good idea about the disease activity and efficiency of the treatment.

Secondary outcome

If the sensivity of increased TARC and MDC serum levels is hight and patients with consistent low TARC and MDC levels are free from failure, measurement of TARC and MDC could replace expensive CT and PET scans.

Study description

Background summary

Morbus Hodgkin is a cancer of the lymphnodes with only a small amount of tumorcells (RS cells) and a large amount of not malignant inflammatory cells. Several studies have indicated that the interaction between the inflammatory cells and the RS cells do play a crucial role in the pathogenesis of Morbus Hodgkin.

Study objective

The aim of this project is a prospective study of blood samples of HL patients to determine the value sensitivity and specificity of increase TARC an MDC serum levels for the early detection of a relapse.

Study design

About 8 - 12 serum samples will be collected before, during and after completion of the therapy and during follow-up. The total follow-up is 5 years so that missing possible relapses is minimized. The total of included patients will be the same as the total patients registered on SKION protocol COG AHOD0031 (METC2004/019), nationally 20-25 pts/year.

Study burden and risks

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

Contacts

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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

Children with Morbus Hodgkin (0-18 yrs) included in SKION protocol COG AHOD0031 (METc2004/019)

Exclusion criteria

Pediatric patients not treated on a COG Hodgkins'Disease protocol

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2007
Enrollment:	90
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	01-08-2007
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	NL12825.042.06