Prognosis of Idiopathic CD4 Lymphocytopenia in children

Published: 02-08-2013
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- The primary research objective is to estimate the prognosis of children affected by ICL. - A secondary research objective is to explore the heredity of ICL between first degree family members.

Ethical review	Not approved
Status	Will not start
Health condition type	White blood cell disorders
Study type	Observational invasive

Summary

ID

NL-OMON38721

Source
ToetsingOnline

Brief title
PROLIC (Prognosis of Idiopathic CD4 Lymphocytopenia in children)

Condition

- White blood cell disorders
- Immune system disorders congenital

Synonym
ICL, Idiopatische CD4 lymphopenia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Heredity, Idiopathic CD4 Lymphocytopenia, Pediatric, Prognosis

Outcome measures

Primary outcome

- CD4 cell counts

- Medical history defined by the questionnaire and medical files provided by

the general practitioner.

Secondary outcome

- Number of first degree family members affected by ICL.

Study description

Background summary

Idiopathic CD4 lymphocytopenia (ICL) is rare immune deficiency. The clinical presentation of ICL can vary between life threatening opportunistic infections to asymptomatic. To date, the aetiology, incidence and prognosis of ICL patients remain largely unknown. Cases of ICL have been described in both adults and children. Past studies to unravel aetiology, incidence and prognosis have mainly been focussed on adult ICL patients, showing high morbidity and mortality in affected patients. Several cases of hereditary ICL have been identified, suggesting a genetic cause for ICL. This aim of this study is to estimate the prognosis of children affected by ICL as well as exploring the heredity of ICL between first degree family members.

Study objective

- The primary research objective is to estimate the prognosis of children affected by ICL.

- A secondary research objective is to explore the heredity of ICL between first degree family members.

Study design

Observational

Study burden and risks

HIV test associated risks:
The chance of a positive HIV test is low considering the population has no risk factors. Also, early ICL diagnosis with specialized treatment in the WKZ may improve prognosis.

ICL diagnosis associated risks:
The diagnosis of ICL may have psychological consequeses. To monitor these consequences the researcher will ask the first three ICL patients and parents to fill in a 'vierdimensionale klachtenlijst'. The results of these forms will be report back to the METC.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Age between 0 to 16
- Lymphopenic two or more occasions, separated by at least a month (identified by pre-clinical screening, see research protocol)
- Good understanding of the Dutch language

Exclusion criteria

- Immunosuppressive co-morbidities explaining lymphopenia
- Immunosuppressive medication explaining lymphopenia
- Unavailability for follow-up research (immigration, mortality)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	150
Type:	Anticipated

Ethics review

Not approved

Date:	02-08-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL42932.041.13