Long term outcome of childhood onset SLE in the Netherlands

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This project aims at documenting long-term disease outcome and quality of life of patients with cSLE in the Netherlands.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON40485

Source
ToetsingOnline

Brief title
CHILL-NL-C

Condition

- Autoimmune disorders

Synonym
Childhood lupus, Juvenile Systemic Lupus Erythematosus, Paediatric Systemic Lupus Erythematosus

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Reumafonds;NVLE

Intervention

Keyword: Childhood Lupus, Fatigue, Quality of Life, Work Participation

Outcome measures

Primary outcome

The primary endpoints are the long term damage measured with the SDI and the quality of life measured with the SF-36. Work participation, coping styles, family planning and fertility, fatigue and psychosocial functioning will also be assessed, as these factors influence quality of life.

Secondary outcome

Secondary endpoints are demographic parameters, socio-economic status, disease characteristics at diagnosis, comorbidities, social support, physical activity and productivity costs.

Study description

Background summary

Systemic Lupus Erythematosus (SLE) is a chronic autoimmune disease with multisystem involvement and wide heterogeneity of disease manifestations. Childhood-onset SLE (cSLE) represents 10-20% of all SLE-cases and is a more severe disease than adult-onset SLE. Children with SLE have higher disease activity at diagnosis and throughout the course of disease including a higher percentage of renal and CNS involvement, more-rapid development of damage over time and a higher mortality rate. Indeed, the majority of cSLE patients will have developed damage due to the disease or its treatment at the age of 20-25 years. Mortality rates have decreased significantly over the past two decades, with 10 and 15 year survival exceeding 85%. However, with a median age of disease onset around 12 years, this means that at the age of 22 to 27 years up to 15% of cSLE patients have died. Dealing with the diagnosis of a lifelong, potentially life threatening disease with an unpredictable course and use of medication that influences life style and physical appearance is difficult, but even more so in puberty, an already challenging time of life on its own. Only a few small studies are available that examined the effect of cSLE on education

and work participation. An American study reported that 35% of patients with cSLE felt that having SLE interfered with their education. At a mean age of 24 years, only 40% of adults with cSLE worked full time. In addition, most adults with cSLE lived on relatively low incomes, with 11-23% living on full-time disability support. Currently there is no information available regarding long term outcome in Dutch cSLE patients.

Study objective

This project aims at documenting long-term disease outcome and quality of life of patients with cSLE in the Netherlands.

Study design

Single centre epidemiological study with optional participation in a National biobank

Study burden and risks

Some questionnaires may be confronting for participants. During the study visit we will inform the participant about the possibilities of psychological help (via their own physician or via the research team) when they feel this is necessary. For the study a single venous puncture is necessary, no other interventions will take place. The risks of emotional stress due to the questionnaires or the single venous puncture are limited. The additional study burden includes the time needed for travel to Rotterdam and the duration of the study visit (2-3 hours).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients diagnosed with SLE according to the ACR-criteria.
Onset of symptoms before the age of 18 (for patients)
Onset of symptoms after the age of 18 (for disease-controls)
Patient is currently older than 18 years
Consent to review medical records
Signed informed consent
Sufficient knowledge of the Dutch language to participate

Exclusion criteria

Refusal to participate
Insufficient knowledge of the Dutch language

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:	Recruiting
Start date (anticipated):	12-12-2013
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	15-08-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-06-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL43004.078.13