DREAMS II Study; HPA axis function and sympathetic nervous system activity in survivors of childhood acute lymphoblastic leukemia

Published: 19-12-2011
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To study HPA axis regulation and sympathetic nervous system activity in survivors of childhood ALL during relaxation and during stress.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Leukaemias
Study type	Observational non invasive

Summary

ID

NL-OMON37326

Source
ToetsingOnline

Brief title
DREAMS II study

Condition

- Leukaemias
- Adrenal gland disorders
- Central nervous system vascular disorders

Synonym
acute lymphoblastic leukemia, leukemia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: KWF;en geld is aangevraagd bij KIKA

Intervention

Keyword: acute lymphoblastic leukemia, HPA axis, sympathetic nervous system

Outcome measures

Primary outcome

HPA axis regulation (cortisol) and sympathetic nervous system activity (blood pressure, heart rate) during relaxation and during the Trier social stress test.

Secondary outcome

The association between HPA axis activity and sympathetic nervous system activity and fatigue and quality of life.

Study description

Background summary

The results of a previous study, the DREAMS I study, showed an increased baseline activity and an enhanced feedback sensitivity of the HPA axis in survivors of childhood ALL. A plausible explanation for the altered HPA axis regulation is the presence of stress, in its various guises. Stress also activates the sympathetic nervous system. Increased sympathetic outflow has clinical implications, since it is associated with the development of the metabolic syndrome. Indeed, it is known that survivors of childhood ALL are at increased risk for the metabolic syndrome.

Study objective

To study HPA axis regulation and sympathetic nervous system activity in survivors of childhood ALL during relaxation and during stress.

Study design

For this multicenter observational study, all 65 participants of our previous DREAMS I study will be invited. During a relaxation period and during the Trier Social Stress Test adapted for children, consisting of a speech task and arithmetic, saliva cortisol levels and sympathetic outflow which is monitored by a non-invasive device will be measured.

Study burden and risks

To perform reliable research on HPA axis function in childhood, this study can not be performed in other subjects than children, for the most part minors. However, the risks of this study are negligible and the possible objections are minimal. The participants will complete a questionnaire at home regarding fatigue and regarding quality of life. In addition, they will be invited for one afternoon in the hospital to perform a Trier Social Stress Test.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

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

All subjects from the VUmc, the UMCU and the UMCN that have been treated according to the Dutch Childhood Oncology Group (DCOG) ALL-9 or ALL-10 protocol and that participated in the DREAMS I study.
Healthy age and sex matched controls, existing of: 1) friends of ALL survivors who participate in the DREAMS study, 2) friends of current ALL patients in the VUmc, 3) friends of survivors of childhood cancer who visit the outpatient clinic late effects of the VUmc.

Exclusion criteria

Prolonged glucocorticoid therapy for other reasons than treatment for ALL.
Chronic health conditions that might influence HPA axis activity.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-01-2012
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-10-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL38017.029.11