Pilot-study: Dexamethasone and function of the HPA axis in children after treatment for Acute Lymphoblastic Leukemia; Relation to sleep

Published: 24-03-2009
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The objectives of this pilot study are to explore differences in sleep and fatigue, and the relation with the function of the HPA axis, between survivors of childhood ALL and healthy controls.

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

Summary

ID

NL-OMON35272

Source
ToetsingOnline

Brief title
Effect of dexamethasone on sleep after childhood ALL

Condition

- Leukaemias
- Adrenal gland disorders

Synonym
leukemia sleepproblems

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Acute Lymphoblastic Leukemie, Dexamethasone, HPA-axis, Sleep

Outcome measures

Primary outcome

Function of the HPA axis will be evaluated with the use of salivatory cortisol

and a low-dose dexamethasone suppression test. Information on sleep, fatigue

and quality of life will be gathered through questionnaires.

Secondary outcome

not applicable

Study description

Background summary

There have been important advances in treatment and survival of children with acute lymphoblastic leukemia (ALL) over the past decades. This success has lead to increased attention for psycho-social functioning in these children. Corticosteroids are an important part of treatment and seem to have an adverse effect on sleep and fatigue, which in turn leads to more psycho-social problems. Sleep problems and fatigue are also common in adult survivors of childhood cancer. In healthy children there is a relation between cortisol and sleep problems. Suppression of the hypothalamic-pituary-adrenal (HPA) axis as a result of high dose steroids has been found in short and long(er) term survivors of ALL. No research has yet explored the relation between the use of steroids, function of the HPA axis and the effect on sleep and fatigue in children with ALL. More understanding of the influence of high dosed steroids on disturbed sleep and increased fatigue, and the relation with suppression of the HPA axis could help improve counselling and quality of life in these children. This pilot study will explore the relation between function of the HPA-axis after high dosed steroids and sleep.

Study objective

The objectives of this pilot study are to explore differences in sleep and fatigue, and the relation with the function of the HPA axis, between survivors of childhood ALL and healthy controls.

Study design

Cross sectional, multi-centre study.
Children treated for ALL according to the national protocol ALL-9 or ALL-10 at the VU University Medical Centre or the national protocol ALL-10 at the Wilhelmina Children's Hospital or the University Medical Center Nijmegen will be eligible. Friends of the patients will provide for an age and sex matched healthy control group. Information on the function of the HPA axis will be collected on two consecutive days. Questionnaires concerning sleep and fatigue will be distributed.

Study burden and risks

Saliva will collected on seven occasions during two consecutive days. Questionnaires will be filled out by parents and children over eight years of age, this will take up to 45 minutes. There are no risks associated with this study. During previous studies in this population, parents and (older) children clearly appreciated the attention for psycho-social issues as a result of ALL treatment. Due to these previous experiences, participation rates in this study are expected to be high.

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

- all children that have been treated according to the ALL-9 (VUmc) or ALL-10 (VUmc, WKZ, UMCN) protocol because of acute lymphoblastic leukemie
- fluent in Dutch

Exclusion criteria

- Down syndrome
- Long-term use of corticosteroids for other reasons than ALL
- other chronic or serious conditions, influencing sleep and/or behavior

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2010
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	24-03-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-08-2010
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	NL26642.029.09