Correlation of White Matter Fractional Anisotropy Measurements at 3T MRI with Neurocognitive Function in Childhood Cancer Survivors: a Pilot Study

Published: 04-01-2007
Last updated: 20-05-2024

AimThe aim of this study is to determine if WMFA measured by DTI at 3T MRI in cancer survivors is a suitable biomarker in children between 8 -16 years of age for treatment induced neurotoxicity and related neurocognitive deficits.

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON30064

Source
ToetsingOnline

Brief title
White matter MRI and cognitive outcome childhood cancer survivors

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Mental impairment disorders

Synonym
brain damage after childhood cancer;

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ONWA

Intervention

Keyword: Childhood cancer survivor, Magnetic resonance imaging, Neurocognitive consequences, White brain matter

Outcome measures

Primary outcome

White matter fraction anisotropy as measured by MR.

Neurocognitive functioning of children including IQ as measured with

intelligence testing and questionaires.

Secondary outcome

The reason for refusal to participate will be registered in order to improve

the design of future ongoing studies concerning brain imaging and

neurocognitive outcome after childhood cancer.

Study description

Background summary

Background
Treatment-induced neurotoxicity by chemotherapy and radiotherapy is a major cause of neurocognitive decline in childhood cancer survivors. Research to investigate potential causes and neuroprotective treatment and intervention methods is mandatory to try improve the neurocognitive outcome of these children. New imaging techniques should be implemented to evaluate the benefit of these strategies in terms of brain development or more specific decrease in white matter damage.

Study objective

Aim

The aim of this study is to determine if WMFA measured by DTI at 3T MRI in cancer survivors is a suitable biomarker in children between 8 -16 years of age for treatment induced neurotoxicity and related neurocognitive deficits.

Study design

WFMA will be studied with the newly developed 3T MRI technique of 20 minutes duration. The neurocognitive functioning of the both patients and control persons will be judged by intelligence testing and speific questionaires for parents and teacher.

Study burden and risks

The participation requires an MRI session of 20 minutes and an intelligence test and questionaires taking about 3 hours. Cautious preparation and coaching of the children will be performed surrounding the MRI and children will be allowed to have their own MRI-picture of their brain. Both investigations should be performed on two separate days in order to be fullfilled properly by the children. The outcome of neurocognitive tests will be available to give advice concerning strong and weak sides of the child in learning aspects. The proposed control persons are most often concerning about class mates with severe illness so we expect that potential candidates will be wiling to particpate to be of help for their classmate as well as other children with cancer. No risk are to be expected for the participants. Participation is completely free and can be ended any moment the child wishes to do so.

Contacts

Public
Academisch Medisch Centrum

PB 22660
1100 DD Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

PB 22660
1100 DD Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Age and sex matched control between 8-16 years selected from the classmates of the patient with an average cognitive performance

Exclusion criteria

1. Psychological contraindications for MR Imaging are claustrophobia and / or need for sedation to perform MRI successfully..
2. Physical contraindication for MR Imaging metallic implants or metallic orthodontic material.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2006
Enrollment:	36
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL13926.018.06