Social cognition in children treated for a brain tumour: A comparative prospective international multi-centre study

Published: 13-04-2011
Last updated: 02-05-2024

Primary Objective: 1) To study impairment and developmental delay in social cognition (and related cognitive functions) caused by brain damage in patients treated for a brain tumour in childhood as compared to a reference group of chronically ill...

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

Summary

ID

NL-OMON39404

Source
ToetsingOnline

Brief title
Social cognition in paediatric brain tumour patients

Condition

- Other condition
- Nervous system neoplasms malignant and unspecified NEC

Synonym
CNS Neoplasm; Cancer

Health condition

neuropsychologische stoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Johanna KinderFonds en Stichting Rotterdams Kinderrevalidatiefonds Adriaanstichting (bedrag van 206.328 euro toegekend);Stichting Kinderoncologie Groningen (bedrag van 36.000 euro toegekend)

Intervention

Keyword: Cranial Radiation Therapy, Emotion recognition, Executive functions, Theory of Mind

Outcome measures

Primary outcome

Change in performance on tests of social cognition from time 1 to time 2.

Secondary outcome

1) Change in reports of social and emotional functioning of patients

themselves, parents and teachers from time 1 to time 2.

2) Influence of Individual medical characteristics on the change in performance

on tests of social cognition from time 1 to time 2.

3) Influence of Socio-economical status (parental education and occupation) on

the change in performance on tests of social cognition from time 1 to time 2

4) Influence of Intelligence level and Executive Functions on the change in

performance on tests of social cognition from time 1 to time 2.

Study description

Background summary

It is known that children treated for a brain tumour often develop deficits in their social and emotional functioning (page 8 and 9 research protocol). We would like to examine how these problems arise and propose underlying neuropsychological deficits in social cognition to be the cause.

From the reviewed literature and clinical practice, the following hypotheses on short and long-term outcome on measures of social cognition have been formulated. *Time 1* refers to neuropsychological testing at the time of diagnosis and *time 2* refers to assessment about 3 years post diagnosis. Patients will be compared to both healthy and chronically ill children (whose central nervous system is not affected by their illness).
1) Children treated for a brain tumour will perform worse than a healthy control group and a control group of chronically ill children on measures of social cognition at time 2, but not at time 1. The deterioration in performance will be influenced by the following factors in such a way that we expect patients with one or more of these factors to have worse performance than those who do not show these characteristics:
a) History of CRT;
b) Site of lesion in diencephalon;
c) History of hydrocephalus and/or PFS.
2) Parents and/or teachers will rate patients as being less socially competent and experiencing more internalizing problems than healthy controls and chronically ill children at time 2, but not at time 1.
3) Performance on tests of ToM will be positively related to executive functions at time 1 and 2.
4) Performance on tests of ToM will be positively related to parent and teacher reports of social competence and environmental factors (parental education and occupation) at time 1 and 2.

Study objective

Primary Objective:
1) To study impairment and developmental delay in social cognition (and related cognitive functions) caused by brain damage in patients treated for a brain tumour in childhood as compared to a reference group of chronically ill children. The focus will be on the neurocognitive basis of such deficits.

Secondary Objectives:
1) To compare performance of BT patients on tests of social cognition to performance of healthy children.
2) Identify disease and treatment factors that can cause impairments and delays in social cognition.
3) Make recommendations for the future development of treatments for patients who have been diagnosed with problems in the social domain.

Study design

The study that will be conducted has a comparative prospective design. Newly diagnosed children with a BT will be assessed at two separate occasions. The first time will be directly after diagnosis and preferably before surgery. Experience from earlier research and clinical work in our department shows this

is feasible. If this is not possible than assessment should take place before the start of any adjuvant therapy. In case of high intracranial pressure, assessment is planned between treatment of hydrocephalus and tumor resection. The second assessment will be conducted three years post diagnosis. Both times parents and teachers will be asked to complete questionnaires. The assessments will be carried out at the department of Paediatric Oncology of the Beatrix Children*s Hospital, UMC Groningen, UMCSt. Radboud Nijmegen, VU medical center Amsterdam and UZ Leuven, Belgium. Simultaneously, chronically ill children diagnosed with CF (recruited from the department of Paediatric Lung diseases of the Beatrix Children*s Hospital, UMC Groningen and UMC St. Radboud) and healthy children will be assessed with the same protocol.

Study burden and risks

The reason for conducting this study with minors is because we want to examine development after treatment for a BT. More specific we wish to study if and how impairments in social cognition arise over time. Children will receive two neuropsychological evaluations. At the first assessment children will always be admitted to the hospital with no extra visit; the second assessment will be combined with other hospital visits as often as possible. Participating children do not undergo any medical procedures and participation will not interfere with their standard medical treatment and neuropsychological evaluation and support. Therefore, the investigators see no risks for participating in this study. The main disadvantage of the study is the time investment. However, as most patients that will participate in this study would have been seen by a neuropsychologist anyway considering current practice in patient care, there is an overlap between tests used in the research study and in the current standard evaluation. Only two tests examining social cognition are additional. Furthermore, mental capacity and age of the patient are taken well into consideration during assessments. Moreover, it is important to mention that children generally enjoy neuropsychological assessments; even shortly after diagnosis, children consider assessments a welcome distraction from medical procedures. The advantage of participating is that, in addition to the (standard) information parent receive about their child*s neuropsychological functioning, specific information about the social and emotional development of their child can be given. Based on the findings parents will be advised about the optimal support and upbringing of their child. The study is considered to be group-related because it could not be conducted without the participation of children diagnosed with a BT.

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

Brain tumour patients:
1) Aged 5-12 years at first assessment
2) Newly diagnosed brain tumour patients that have not yet received adjuvant therapy
3) Stable medical condition;Healthy controls:
1) Aged 5-12 years at first assessment ;CF patients:
1) Aged 5-12 years at first assessment
2) Stable medical condition

Exclusion criteria

Brain tumour patients:
1) Diagnosed with a disorder of the autistic spectrum, not related to the tumour (Autism, Asperger*s Syndrome or Pervasive Developmental Disorder not otherwise specified).
2) History of other brain disease or neurological condition interfering with normal development.
3) No native Dutch speaker

4) Severe sensory handicaps and/or behavioural problems interfering with reliable neuropsychological assessment
5) IQ below 70
6) Poor prognosis and life expectancy less than 1 year.;Healthy controls:
1) Diagnosed with a disorder of the autistic spectrum (Autism, Asperger*s Syndrome or Pervasive Developmental Disorder not otherwise specified).
2) History of other brain disease or neurological condition interfering with normal development.
3) No native Dutch speaker
4) Severe sensory handicaps and/or behavioural problems interfering with reliable neuropsychological assessment.
5) IQ below 70;CF patients:
1) Diagnosed with a disorder of the autistic spectrum (Autism, Asperger*s Syndrome or Pervasive Developmental Disorder not otherwise specified).
2) History of other brain disease or neurological condition interfering with normal development.
3) No native Dutch speaker
4) Severe sensory handicaps and/or behavioural problems interfering with reliable neuropsychological assessment.
5) IQ below 70

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:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2011
Enrollment:	39
Type:	Actual

Ethics review

Approved WMO Date:	13-04-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-08-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-06-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-10-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-12-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT01599052
CCMO	NL31489.042.10