fNIRS in children with traumatic brain injury - relation with outcome

Published: 03-02-2015
Last updated: 21-04-2024

This study is part of a prospective cohort study in the University Medical Center Groningen aimed at the determination of prognostic factors for outcome of children with TBI. The study is a pilot study to determine the value of fNIRs for detection...

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

Summary

ID

NL-OMON40627

Source
ToetsingOnline

Brief title
fNIRs in children with TBI

Condition

- Other condition

Synonym
traumatic brain injury

Health condition

traumatisch hersenletsel

Research involving
Human

Sponsors and support

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

Intervention

Keyword: adolescents and children, fNIRS, outcome, traumatic brain injury

Outcome measures

Primary outcome

Evaluate the applicability of fNIRS measurements in children with TBI, obtained

in the acute phase after trauma and to verify its prognostic relevance for

outcome at 6 months.

Secondary outcome

Secondary objectives are to:

1) evaluate if cerebral hemodynamical changes in adolescents are related to

cognitive performance

2) evaluate the relation between cerebral hemodynamics in the acute phase and

clinical subtypes of TBI (history and genetically) in pediatric TBI;

Study description

Background summary

Traumatic brain injury (TBI) is one of the most important causes of morbidity and mortality in children. In the Netherlands, annually 12000 children are seen at the Emergency Department after sustaining a TBI. The application of most cerebral imaging techniques in the pediatric population is hindered by several disadvantages and side effects. The use of computed tomography (CT) should be restricted, if possible, in the pediatric population because of the harmful X-ray radiation exposure. With the use of functional Near Infrared Spectroscopy (fNIRS) it is possible to obtain in a non-invasive manner information about cerebral hemodynamics, without the disadvantages of X-ray exposure or motion

susceptibility. Furthermore, progressive edema in the acute phase might be related to genetic profiles.
The primary objective of this study in children with TBI is to evaluate the prognostic value of fNIRS values obtained in the acute phase of injury. Combining this device with the simultaneous performance of cognitive tests in the group of adolescents (10-18 years), will help to determine if there are cognitive difficulties after TBI in relation with hemodynamical changes.

Study objective

This study is part of a prospective cohort study in the University Medical Center Groningen aimed at the determination of prognostic factors for outcome of children with TBI. The study is a pilot study to determine the value of fNIRs for detection of hemodynamical changes in the acute phase after injury in relation with outcome.

Study design

This study is part of a prospective cohort study in the University Medical Center Groningen aimed at the determination of prognostic factors for outcome of children with TBI. The study is a pilot study to determine the value of fNIRs for detection of hemodynamical changes in the acute phase after injury in relation with outcome as measured with the GOSE for children.

Study burden and risks

Measurements in this study do not have adverse consequences for those involved, and there are no risks associated with participation. The time-consuming burden will be acceptable as the duration of the fNIRS measurement for hemodynamical evaluation takes 15 minutes. When patients have to perform an additional cognitive test with the FNIRS assessment, the duration is 20 minutes per session. In addition, questionnaires have to be filled out on three occasions by the parents, i.e. during admission and at the outpatient department which is part of care as usual.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific

Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

traumatic brain injury
GCS 3 -15
age 1 - 18 years
admittance to the ward
informed consent legal representive

Exclusion criteria

no follow-up
comorbidity
no comprehension of dutch language
psychiatric illness
earlier admission for tbi
limitations for fNIRS (anemia, hypercapnia, hypoxia)

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-03-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	03-02-2015
Application type:	First submission
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
CCMO	NL50825.042.14