Endocrine- , emotional development study

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To identify risk factors that might contribute to the development of post-traumatic HHD in children in order to reduce the lag-time between onset and diagnosis for future patients. To investigate the level of functioning and the quality of life of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON31275

Source
ToetsingOnline

Brief title
EED study

Condition

- Hypothalamus and pituitary gland disorders
- Central nervous system vascular disorders
- Developmental disorders NEC

Synonym
brain injury resulting in hormone deficiency, post-head trauma hypopituitarism

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Pfizer

Intervention

Keyword: emotional physical development, endocrine dysfunction, traumatic brain injury

Outcome measures

Primary outcome

Type of pituitary dysfunction in relationship with TBI in children in the

Netherlands

Risk factors and mechanisms for HHD in children withTBI

Secondary outcome

Emotional and physical development and functioning in children after a TBI.

Quality of life

Study description

Background summary

See page 8 and further in protocol.

Study objective

To identify risk factors that might contribute to the development of
post-traumatic HHD in children in order to reduce the lag-time between onset
and diagnosis for future patients.
To investigate the level of functioning and the quality of life of children,
young adult and adolescents 8 years after a traumatic skull/ brain injury.

Study design

See page 13 of the protocol

Study burden and risks

Risk are low: one venapunction and one X ray left hand (bone-age).

Patients might benefit from this trial, because patients with TBI,

participating in this study, can be diagnosed in an earlier stage with possible effects of this TBI, like endocrine dysfunction. This was described in adult patients, but only in case reports in children.
It is important that children with TBI are followed up as a group, because it is essential to describe the effects of this TBI on their development. This can only be done in children who suffered from TBI. Often disorders post accident are related to the accident itself, but not related to possible endocrine disorders following the brain injury.

Contacts

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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

traumatic brain injury; children < 18 years; Glasgow coma scale < 9.

Exclusion criteria

Not part of the IMPACT study 2000/2001

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-08-2008
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	13-12-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL19529.078.07