Association of Chronic Posttraumatic Fatigue and Pituitary Hormone Deficiencies after Traumatic Brain Injury

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ObjectiveTo assess the prevalence of PHD and chronic fatigue in Dutch TBI patients, and to study the relationships between the various aspects of chronic fatigue and PHD, with particular emphasis on the association between chronic fatigue, and…

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON32656

Source
ToetsingOnline

Brief title
Chronic Fatigue and Pituitary Hormone Deficiencies in TBI

Condition

- Other condition
- Hypothalamus and pituitary gland disorders
- Structural brain disorders

Synonym
fatigue, traumatic brain injury

Health condition

persisternde cognitieve en fysieke vermoeidheid na letsel

Research involving

Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Groot Klimmendaal Arnhem en ziekenhuis Rijnstate Arnhem
Source(s) of monetary or material Support: Revalidatiecentrum Groot Klimmendaal

Intervention

Keyword: Fatigue, Hormone deficiencies, Pituitary deficiencies, Traumatic Brain Injury

Outcome measures

Primary outcome

Main study parameters

fatigue score (CIS20R Sub),

Secondary outcome

Severity of TBI (GOSE), demographic questionnaire, Cognition (TOSSA,TODA),

emotion and depression (HADS), general quality of life in TBI (QOLIBRI),

hypogonadism score (AMS), growth hormone deficiency related quality of life

(AGHDA-QOL), acceptance and coping (AAQ), sleep quantity and quality (Sleep

Q.), physical activity score (FAI), physical performance (Åstrand), serum

hormone levels measured between 8.00 h and 10.00h AM (free T4, T3, TSH,

cortisol, ACTH, prolactin, sex hormones, SHBG, IGF-I, IGF-BP3), and the maximal

GH response to the growth-hormone releasing hormone-Arginine test (GHRH-Arg),

body composition by dual energy X-ray absorptiometry.

7 variables (cognition, emotional state, coping-acceptance state, condition,

sleep quality/quantity, activity state, hormonal state will be used tot

determine their contribution to the chronic post TBI fatigue.

Study description

Background summary

SUMMARY
Chronic Fatigue and Pituitary Hormone Deficiencies in Traumatic Brain Injury
Rationale
The incidence of traumatic brain injury (TBI) in the Netherlands is 187 per 100.000 inhabitants/year (19). TBI occurs more frequently in males than females, the male to female ratio is 3:21 (19). Chronic fatigue will develop in 43 - 73% of cases (1). For the Netherlands this implies that 22.000 of the yearly 30.000 TBI patients will develop chronic fatigue. It adversely affects quality of life, often to a severe degree.
The aetiology of chronic fatigue in TBI is multi-factorial. It may be related to cognitive impairment , (21,22), physical impairment (8), anxiety, depression (15) and insomnia (13) .To some extent posttraumatic fatigue may result from pituitary hormone deficiencies (PHD) caused by traumatic pituitary damage3,4 (3,4,6,7,11,12,16,17,18). One year after TBI 22 - 37% of the patients has one or more PHD*s11 (7), the gonadal axis is involved in 15% and 10 - 20% is growth hormone deficient13 (12). This high percentage of PHD is explained by the effect of direct trauma or posttraumatic oedema which may lead to interruption of the hypothalamo-hypophysial portal blood supply and subsequent infarction of the pituitary12 (11).
In view of the high prevalence of PHD in TBI and the expectation that treatment of PHD may substantially improve mental and physical performance, it has been recommended that all TBI patients should be screened for PHD.10 However, at present screening for PHD is not routinely performed in post TBI rehabilitation centres. Consequently, PHD is likely to be under diagnosed, and many patients will not receive adequate hormonal replacement therapy (HRT).

Study objective

Objective
To assess the prevalence of PHD and chronic fatigue in Dutch TBI patients, and to study the relationships between the various aspects of chronic fatigue and PHD, with particular emphasis on the association between chronic fatigue, and gonadal and growth hormone deficiencies.

Study design

Study design cross-sectional observational study, a random sample from a predefined population with TBI (sample size N=120), screened after at least one year following TBI, using clinical assessment instruments and biochemical analysis of hormonal parameters.

Study burden and risks

not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria

* Patients treated in the TBI department of the rehabilitation centre of Groot Klimmendaal between 2000 and 2008
* Males and females age 18 to 50 years.
* Confirmed diagnosis of previous TBI of at least one year
-TBI that required hospitalization
-originally diagnosed by neurological assessment and MRI or CT
-Extended Glasgow Coma Scale at time of inclusion >=5
* Subjects who are willing and able to comply with scheduled visits and laboratory tests.
* Evidence of a personally signed and dated informed consent document indicating that the subject or a legally acceptable representative has been informed of all pertinent aspects of the trial.

Exclusion criteria

Exclusion criteria
* Hypothalamic/pituitary disease diagnosed prior to TBI
* Brain injury of non traumatic origin
* History of cranial irradiation
* Known drug or alcohol abuse
* Present or past non-TBI related medical (diagnosed by a medical specialist) or psychiatric conditions (according to DSM IV criteria) that impair the fulfilment of study requirements and/or interfere with the evaluation of study objectives by probable independent effects on quality of life or neuropsychological functioning.
* Severe neuromuscular disability or additional co-morbidity (heart, pulmonary, kidney, and liver disease) which causes such a condition deficit that it is impossible to fulfil the physical condition Åstrand test by bike.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NL24522.072.08