Hypopituitarism after Severe Traumatic Brain Injury, an observational study

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To study the prevalence of hypopituitarism and osteoporosis in patients 5 tot 10 years after severe traumatic brain injury

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

Summary

ID

NL-OMON32099

Source
ToetsingOnline

Brief title
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Condition

- Hypothalamus and pituitary gland disorders
- Bone disorders (excl congenital and fractures)

Synonym
hypopituitarism, loss of function of the pituitary gland

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: research fonds afdeling endocrinologie

Intervention

Keyword: Hypopituitarism, Osteoporosis, performance, Severe traumatic brain injury

Outcome measures

Primary outcome

Primary aims:

1- To investigate the prevalence of hypopituitarism in patients after traumatic brain injury.

2- To investigate the prevalence of osteoporosis in this TBI population.

Secondary outcome

Secondary aims:

3- To investigate possible prognostic factors for development of hypopituitarism after severe traumatic brain injury.

4- To compare physical and neuropsychological performance in patients with and without hypopituitarism after severe TBI.

5- To study bone mineral density in patients after severe traumatic brain injury and study separately the bone mineral density in patients with and without hypopituitarism after traumatic brain injury and compare this with the normal population.

Study description

Background summary

Traumatic brain injury (TBI) is one of the most important causes of disability and mortality in western countries. In the Netherlands about 30.000 mainly young people are annually diagnosed with traumatic brain injury. At least 300.000 people are thought to have had traumatic brain injury in the past. 1 Sequelae from traumatic brain injury result in a reduced quality of life for the patient and his or her environment and also high costs for society. Hypopituitarism, or deficiency of one or more pituitary hormones, is a known complication of traumatic brain injury. The posterior pituitary lobe often shows transient loss of function, whereas the anterior pituitary lobe often has permanent loss of function. In recent years a lot of research has been done regarding the prevalence of hypopituitarism after TBI. There seems to be a time dependent loss of function. The pituitary function of patients who develop hypopituitarism in the acute phase (within 3 months after TBI) will sometimes normalize in the chronic phase after TBI, but also new cases will occur in the chronic phase. 2,3,4,5 These recent studies show that hypopituitarism after TBI is a more frequent complication than thought before, found in about 25-30% of patients with severe head trauma. 6,7,8,9
A lot of the persisting cognitive, physical and emotional complaints and deficits after TBI are thought to be caused by a post-contusion or post-traumatic syndrome. These problems could however also be caused by hypopituitarism. Symptoms of hypopituitarism can be difficult to recognize in this patient population and as recent research has shown, hypopituitarism appears to be an underestimated problem.
Treatment with hormones is easy once hypopituitarism is diagnosed and could lead to a significant improvement of neuro-psychological and physical performance of these patients.

Bone structure and strength depend on mechanical loading, adequate nutrition and hormonal balances. No research has been done on the incidence of osteoporosis in patients with traumatic brain injury, although they are at increased risk for developing osteoporosis. Most patients are immobilized and institutionalized with lack of sun exposition and as mentioned above there seems to be an increased incidence of hypopituitarism. Furthermore nutritional deficiency, medication and autonomic dysfunction can cause loss of bone mass. 10

References;

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7 Aimeretti A, Ambrosio MR, di Somma C, Fusco A, Cannavo S, et al. Traumatic brain injury and subarachnoid haemorrhage are conditions at high risk for hypopituitarism: screening study at 3 months after brain injury. Clin Endocrinol 2004; 61: 20-326
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Study objective

To study the prevalence of hypopituitarism and osteoporosis in patients 5 tot 10 years after severe traumatic brain injury

Study design

Cross-sectional observational study

Study burden and risks

The burden consists of coming to the poliklinic, having an interview and fysical examination. Furthermore participation in a questionair, undergoing an ultrasound of the healbone, bone density measurement and bloodtest. If the bloodtest shows signs of hormone deficiency adittional tests are necesarry to examine the function of the pituitary gland.

There are no significant risks attached to participating in the study. There are however possible benefits for participants. Hypopituitarism and osteoporosis are easy to treat. Hormone supplements in hypopituitarism can improve cognitive, fysical and neuro-psychological performance. Treatment of osteoporosis can prevent fractures and bone deformation.

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

Men and women 18 to 70 years of age
TBI (traumatic brain injury) in past
GCS is known at admission
CT or MRI has been made after admission

Informed consent subject

Exclusion criteria

Pregnancy
Pre*existing hypopituitarism or risk factors for hypopituitarism
Pre*existing neuro*psychological and/or physical deficit which makes taking part in study and following protocol impossible
Corticosteroid use
Alcohol abuse and/or drug use

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-10-2008
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	09-07-2008
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	NL21877.029.08