Hypopituitarism in patients after subarachnoid hemorrhage: screening and treatment

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To determine the incidence of hypopituitarism in patients after SAHTo identify neurological parameters that predict hypopituitarism after SAHTo determine the value of a Ghrelin test shortly after SAH, to identify subjects with GHD.To determine the...

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

Summary

ID

NL-OMON39410

Source
ToetsingOnline

Brief title
HIPSS

Condition

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

Synonym
hemorrhagic stroke, subarachnoid hemorrhage

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: hersenstichting,Pfizer

Intervention

Keyword: growthhormone defeciency, hypopituitarisme, subarachnoidal hemorrhage(SAH), therapy

Outcome measures

Primary outcome

the incidence and potential riskfactors of hypopituitarism in patients after a

SAB

potential base line SAB riskfactors: hydrocephalus, extravasated blood, delayed

cerebral ischemia, glasgow coma scale in relation with hypopituitarism.

Secondary outcome

1) Incidence and potential riskfactors of growthhormone defeciency in patients

after SAB.

2) Value of Ghrelin test for GHD shortly after SAH

3) Difference in physical functioning in patients with hypopituitarism and the

control group, identified by different specific questionnaires.

4) Difference in quality of life in patients with hypopituitarism and the

control group, identified by different specific questionnaires.

5) Difference in level of everyday physical activity and physical funcitoning

(max. oxygen consumption and muscle strength) post SAH and healthy controls.

Study description

Background summary

Spontaneous subarachnoidal hemorrhage (SAH) occurs with an incidence of six cases per 100.000 patient years, with a case mortality amounting to 50% (1). In patients who survived SAH, high rates of functional limitations are found along with quality-of-life impairment, such as fatigue, decreased mobility, loss of motivation, reduced independence in activities of daily living and decreased social functioning (1,2).
The residual functional problems in patients after SAH are often unexplained, but may largely resemble those occurring in patients with untreated hypopituitarism. Corticotrophin and TSH deficiency may present with symptoms such as fatigue, weakness, headache, altered mental activity or impaired memory. Symptoms attributable to Growth Hormone deficiency include lack of vigor, decreased exercise tolerance and decreased social functioning with loss of quality of life (2).
Recent studies in long-term survivors of SAH have shown varying incidences (from 20 up to 50%) of hypopituitarism, with growth hormone deficiency (GHD) occurring in 15 - 25% of patients (3,2,4,5). This neuroendocrine dysfunction could be the result of damage to the hypothalamic/pituitary system caused by post hemorrhagic local tissue pressure, toxic effects of the extravasated blood, ischemia caused by vasospasm, high intracranial pressure, hydrocephalus or local destruction during cerebral surgery. At present, it is not possible to identify which SAH patients are at risk of developing hypopituitarism. The clinical effects of optimal hormone replacement therapy on residual symptoms in SAH patients is unknown.

Measuring Healthy controls.
Adequate norm values for the SAH patients concerning fitness, muscle strength and activity pattern are lacking. However, these norm values are necessary to interpret the results for evaluating the effects of SAH on physcial functioning. This knowledge can be used to optimise rehabilitation programs after SAH which may reduce the residual complaints.

Study objective

To determine the incidence of hypopituitarism in patients after SAH
To identify neurological parameters that predict hypopituitarism after SAH
To determine the value of a Ghrelin test shortly after SAH, to identify subjects with GHD.
To determine the impact of hypopituitarism on physical functioning, activity pattern and participation.
To evaluate the effect of GH replacement on residual functional physical fitness, fatigue and quality of life.

To evaluate physical functioning (cardiorespiratory and neuromuscular fitness), activity pattern and fatigue in patients post SAH.

Study design

This is a prospective clinic-based cohort study

Study burden and risks

The study consists of 7 visits to our hspital for patients with hypopituitarism. Patient without hypopituitaris only need to bring two vists to our hospital. During these visits which will last for 66 weeks, we will evaluate the patients by specific questionnaires. Bloodsampling will take place according to the study flowchart in every visit. Two of the visits in week 24 and 60 will take longer than normal because of more extensive evaluation, the visit in week 24 is only for patients with hypopituitarism and in week 60 for all the patients included in the study. Patients with hypopituitarism will be treated by the endocronologist comitted to this study.

Measuring Healthy controls.
All tests can be taken during one session of approximately 2,5 hours. The measurements take place in the human movement laboratory of the department of Rehabilitation Medicine and Physical Therapy of Erasmus MC. Controls will be screened using a Par-Q quenstionaire, a Sportmedical questionaire and a physical examintion before maximal testing.

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

Subarachnoid hemorrhage
Age >= 18 years
Discharge from ICU
Signed and dated informed consent document;Controls will be patient-matched on age (+/- 5 years) and gender.

Exclusion criteria

Any hypothalamic/pituitary disease diagnosed prior to SAH.
History of cranial irradiation
Prior significant trauma capitis
Another significant intracranial lesion (apart from SAH or its sequellae)
Any other medical or psychiatric condition or laboratory abnormality that may impose a risk for participation in the study or interfere with the interpretation of the study (according to the judgment of the investigators).;Exclusion criteria healthy controls: individuals with deficits which affect physical fitness or activity (eg amputations, hip/knee prosthesis, cognitive problems), individuals at risk for health issues because of maximal testing (according to the Par Q checklist).

Study design

Design

Study type: Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2009
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-07-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-11-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-07-2013
Application type:	Amendment
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	NL22291.078.08