Hypopituitarism in patients after subarachnoid hemorrhage: Screening and treatment.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23702

Source
Nationaal Trial Register

Brief title
HIPSS

Health condition

Hypopituitarism
in patients after
subarachnoid hemorrhage

Sponsors and support

Primary sponsor: erasmus medical centre
Source(s) of monetary or material Support: Unie, vakministeries of bedrijven), namelijk: hersenstichting
Farmaceutische industrie: Pfizer

Intervention

Outcome measures

Primary outcome

1. To determine the prevalence of hypopituitarism in patients after SAH;

2. To identify neurological parameters that predict hypopituitarism after SAH;

3. To determine the value of a Ghrelin test shortly after SAH, to identify subjects with GHD.

Secondary outcome

1. To determine the impact of hypopituitarism on physical functioning, activity pattern and participation;

2. To evaluate the effect of GH replacement on residual functional physical fitness, fatigue and quality of life.

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

Study objective

The aim of the present study is:

1. To determine the incidence of hypopituitarism in subjects after SAH, using a routine hormonal screening protocol;

2. To identify prognostic neurological determinants for the development of hypopituitarism following SAH;

3. To evaluate the value of the GRPH-6 test in the acute phase of SAH in determinating the presence of growth hormone deficiency.

Study design

1. Visit 1: During admission for SAH;

2. Visit 2: Week 12 (3 months after SAH);

3. Visit 3: Week 18 (6 weeks after start hormone suppletion)
(Only for patients with established hormone deficiency);

4. Visit 4: Week 24 (6 months after SAH);

5. Visit 5: Week 28 (4 weeks after start GH-suppletion);

6. Visit 6: Week 44 (20 weeks after start GH-suppletion);

7. Visit 7: Week 60 (36 weeks after start GH-suppletion).

Intervention

Replacement of hormone defeciencies as required.

Contacts

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Eligibility criteria

Inclusion criteria

1. Subarachnoid hemorrhage;

2. Signed and dated informed consent document.

Exclusion criteria

Subjects with any of the following items will be excluded from the study:

1. Any hypothalamic/pituitary disease diagnosed prior to SAH;

2. History of cranial irradiation;

3. Prior significant trauma capitis;

4. Another significant intracranial lesion (apart from SAH or its sequellae);

5. 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).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-01-2009
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-10-2009
Application type:	First submission

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
NTR-new	NL1968
NTR-old	NTR2085
Other	METC : MEC-2008-288
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A