Hypopituitarism in patients after subarachnoid hemorrhage: Screening and treatment.

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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…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23702

Bron
Nationaal Trial Register

Verkorte titel
HIPSS

Aandoening

Hypopituitarism
in patients after
subarachnoid hemorrhage

Ondersteuning

Primaire sponsor: erasmus medical centre
Overige ondersteuning: Unie, vakministeries of bedrijven), namelijk: hersenstichting
Farmaceutische industrie: Pfizer

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

Replacement of hormone defeciencies as required.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Subarachnoid hemorrhage;

2. Signed and dated informed consent document.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-01-2009
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-10-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1968
NTR-old	NTR2085
Ander register	METC : MEC-2008-288
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A