Fatigue after ischemic stroke: association with pituitary dysfunction

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27430

Source
NTR

Brief title
PIT-FAST

Health condition

ischemic stroke
fatigue
pituitary dysfunction

Sponsors and support

Primary sponsor: H.M. den Hertog, neurologist at Medisch Spectrum Twente, Enschede, the Netherlands.
Source(s) of monetary or material Support: Neurology Department, Medisch Spectrum Twente, Enschede, the Netherlands.

Intervention

Outcome measures

Primary outcome

To assess the difference in prevalence of pituitary dysfunction between patients with and

patients without fatigue after ischemic stroke.

Secondary outcome

1. To assess the time course of pituitary dysfunction after ischemic stroke.

2. To assess predictors of pituitary dysfunction after ischemic stroke, including stroke severity, stroke location and demographic factors.

3. To assess the association between pituitary dysfunction and depression, cognitive performance and functional status after ischemic stroke.

4. To assess independent predictors for poststroke fatigue, including pituitary dysfunction, depression, use of medication, comorbidity, laboratory disturbances, pain, illness representation, stroke location, stroke severity and sleep apnoea disorder.

5. To assess the association between fatigue and functional status after ischemic stroke.

Study description

Study objective

The hypothesis is that poststroke fatigue is associated with pituitary dysfunction.

Other factors associated with poststroke fatigue, e.g. sleep apnoea and laboratory dysfunction, will be investigated as well.

Study design

Patients will be assessed at enrolment, and at 3 months, 6 months and 12 months thereafter.

Intervention

Besides standard treatment at enrolment, patients will undergo a general physical examination, a questionnaire, a cognitive performance test, a polygraph, a standardized fasting blood test and a routine hormone screening protocol. In case of abnormal hormonal values, additional tests will be performed to assess the level of dysfunction.

Contacts

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Eligibility criteria

Inclusion criteria

A subject must meet all of the following criteria:

- 18 years or older;

- NIHSS score12 of ¡Ý 2;

- be expected to be discharged to a rehabilitation unit or to home.

Exclusion criteria

Patients will be excluded when they:

- are being treated with chemotherapeutics;

- are receiving (oral or intravenous) corticosteroid therapy for more than 1 month (not: inhalation corticosteroids);

- are pregnant;

- are not able to complete a questionnaire due to severe aphasia, non-Dutch speaking or severe cognitive disturbances;

- have a history of hypothalamic/pituitary disease that significantly affects the study results, e.g. Cushing¡¯s disease, cranial irradiation or another significant intracranial lesion, multiple sclerosis, chronic fatigue syndrome and/or psychiatric condition that interferes with interpretation of the study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-10-2015
Enrollment:	118
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 47027
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5182
NTR-old	NTR5330
CCMO	NL52674.044.15
OMON	NL-OMON47027

Study results