Pituitary dysfunction in association with fatigue after ischemic stroke

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Primary Objective: To assess the difference in prevalence of pituitary dysfunction between patients with and patients without fatigue after ischemic stroke. Secondary Objectives: 1. To assess the time course of pituitary dysfunction after ischemic...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON47027

Source
ToetsingOnline

Brief title
PIT-FAST

Condition

- Central nervous system vascular disorders

Synonym
ischemic stroke

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: het onderzoek wordt volledig gefinancieerd met afdelingsgeld

Intervention

Keyword: fatigue, ischemic stroke, pituitary dysfunction

Outcome measures

Primary outcome

The prevalence of pituitary dysfunction and fatigue after ischemic stroke.

Secondary outcome

Other study outcomes are depression, cognitive performance, functional status, laboratory dysfunction, pain, illness representation, stroke location, stroke severity, stroke classification, cardiovascular risk factors, sleep apnoea and sleepiness.

Study description

Background summary

Fatigue affects between 36-77% of stroke survivors at different time intervals and could be a constraint for rehabilitation. The exact etiology of post stroke fatigue is unknown. One possible explanation for fatigue is pituitary dysfunction. A better understanding of the processes involved in poststroke fatigue may assist in developing rational interventions and improve outcome. We aim to assess the role of pituitary dysfunction in fatigue after ischemic stroke with a routine hormone screening protocol. A secondary aim is to study other determinants of fatigue after ischemic stroke, including depression, use of medication, laboratory disturbances and sleep apnoea disorder. Furthermore, we would like to assess the association between appearance of infra-slow activity, functional outcome and fatigue after ischemic stroke.

Study objective

Primary Objective:
To assess the difference in prevalence of pituitary dysfunction between patients with and patients without fatigue after ischemic stroke.

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

2. To assess predictors of pituitary dysfunction after ischemic stroke.
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.
6. To assess the association between appearance of infra-slow activity, functional outcome and fatigue after ischemic stroke.

Study design

This is a prospective observational cohort study.

Study burden and risks

Patients will be assessed at enrolment, and at 3 months, 6 months and 12 months thereafter, with an estimated duration of 1 hour for each visit. Besides standard treatment at enrolment, during all assessments patients will undergo a general physical examination, a questionnaire and a routine hormone screening protocol. In case of abnormal hormonal values, additional tests will be performed to assess the level of dysfunction. At inclusion, EEG-registration of 1 hour will be performed. At inclusion and at 12 months a standardized blood test will be performed for blood count, renal and liver function, glucose and CRP. At 3 months and 12 months a cognitive function test and attention span test will be performed. All patients will undergo a polygraph at 12 months. A subgroup will ondergo an extended neuropsychological test. Since this is an observational study with no invasive diagnostic or therapeutic interventions, we judge the chance of an adverse event to be low.

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

Patients will be eligible for inclusion if they are 18 years or older and have a clinical diagnosis of first ever ischemic stroke. Patients should have an NIHSS score of * 2 and be expected to be discharged to a rehabilitation unit or to home.

Exclusion criteria

Patients will be excluded when they:
- are 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
*- psychiatric condition that interferes with interpretation of the study

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-11-2015
Enrollment:	118
Type:	Actual

Ethics review

Approved WMO Date:	17-09-2015
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	14-07-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	17-04-2018
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27430
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL52674.044.15
OMON	NL-OMON27430