EEG in patients with acute stroke: detection of secondary deterioration and outcome prediction

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

Summary

ID

NL-OMON47253

Source
ToetsingOnline

Brief title
EEG in acute stroke

Condition

- Central nervous system vascular disorders

Synonym
cerebrovascular accident, ischemic stroke

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cortical spreading depression, EEG, Ischemic stroke, Secondary deterioration

Outcome measures

Primary outcome

The main study parameters are (1) neurological deterioration during hospital admission (=primary outcome measure), and (2) incidence of EEG patterns that indicate cortical spreading depressions, epileptiform activity, infraslow activity, of disturbed functional connectivity in the contralesional hemisphere.

Secondary outcome

Secondary outcome measures will be functional outcome defined as the score on the mRS, the Barthel index, and major depressive disorder 6-8 weeks after discharge.

Study description

Background summary

14-30% of patients with acute stroke deteriorate during hospital admission. The pathophysiological mechanisms leading to secondary deterioration are often unknown and therapeutic consequences are lacking. It has been shown that cortical spreading depressions (CSDs), infra-slow oscillations, and epileptic activity may have detrimental effects. Remote network changes in the contra-lesional hemisphere probably play a role in functional recovery and incidence of major depressive disorder. We will study the incidence of these phenoma with electroencephalography (EEG) in patients with acute stroke and relate these to secondary deterioration, functional recovery and major depressive disorder.

Study objective

Primary objective is to investigate whether secondary deterioration after acute

stroke is associated with CSD, infraslow activity, or epileptiform activity. Secondary objectives are (1) to assess the feasibility of continuous full-band EEG to measure CSD, infraslow activity, and epileptiform activity in patients with acute stroke; (2) to explore (additional) signal analysis techniques for detecting CSD, relevant infraslow activity patterns, or epileptiform activity; (3) to generate hypotheses about which patients with acute stroke are at risk for secondary deterioration; (4) to relate remote network changes in the contra-lesional hemisphere to fuctional recovery and major depressive disorder. (5) To estimate the additional value of high density EEG (64 electrodes) for analyses of brain functional connectivity measures in stroke patients as compared with healthy controls.

Study design

This is a prospective observational cohort study of 80 adult patients with acute stroke admitted to the stroke unit of Medisch Spectrum Twente or Rijnstate Hospital. In addition, a control group of 10 healthy subjects will be monitored with EEG for 20-30 minutes. to serve as a reference for the high density EEG measurements.
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Study burden and risks

Participation implies EEG monitoring for 20-30 minutes, and a diagnostic interview 6-8 weeks after discharge. EEG is routine, everyday investigation. Serious or major adverse events are not expected and the risk of an increase of morbidity or mortality is considered negligible. In case of incidental findings in the control group, these findings are communicated to the healthy subjects, unless the subjects notified not wanting to be informed about this finding.

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

-Age 18 years or older
-Diagnosis of acute stroke
-Possibility to start EEG monitoring within 48 hours from symptom onset
-Admission to the stroke unit
-Neurological deficit with a National Institutes of Health Stroke Scale (NIHSS) score *2
-Degree of disability before stroke on modified Rankin Scale (mRS) score <3 (no symptoms at all, no significant disability, or a slight disability)

Exclusion criteria

- Any progressive brain illness, such as a brain tumor or neurodegenerative disease
-Expectation that the patient will die due to the stroke

Study design

Design

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

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-11-2014
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	23-09-2014
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	29-03-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	23-03-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	27-03-2018
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

No registrations found.

In other registers

Register	ID
CCMO	NL50284.044.14