Electroencephalography for the triage of stroke patients in the ambulance.

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To develop and validate an algorithm based on dry electrode cap EEG data that accurately determines the likelihood of an LVO-a in patients with a suspected AIS in the ER.

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

Summary

ID

NL-OMON50916

Source
ToetsingOnline

Brief title
EEG4STROKE

Condition

- Central nervous system vascular disorders

Synonym
large vessel occlusion in the anterior circulation (LVO-a). Stroke.

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ambulance, EEG, stroke, triage

Outcome measures

Primary outcome

Faster and better triage of patients with a large vessel occlusion in the

anterior circulation (LVO-a) in the ambulance. So that patients with an LVO-a

are brought to the right hospital immideately.

Secondary outcome

Not applicable.

Study description

Background summary

Endovascular thrombectomy (EVT) is standard treatment for acute ischemic stroke (AIS) if there is a large vessel occlusion in the anterior circulation (LVO-a). Because of its complexity, EVT is performed in selected hospitals only. Currently, approximately half of EVT eligible patients are initially admitted to hospitals that do not provide this therapy. This delays initiation of treatment by approximately an hour, which decreases the chance of a good clinical outcome. Direct presentation of all patients with a suspected AIS in EVT capable hospitals is not feasible, since only approximately 7% of these patients are eligible for EVT. Therefore, an advanced triage method that reliably identifies patients with an LVO-a in the ambulance is necessary. Electroencephalography (EEG) may be suitable for this purpose, as preliminary studies suggest that slow EEG activity in the delta frequency range correlates with lesion location on cerebral imaging. Use of dry electrode EEG caps will enable relatively unexperienced paramedics to perform a reliable measurement without the EEG preparation time associated with *wet* EEGs. Combined with algorithms for automated signal analysis, we expect the time of EEG recording and analysis to eventually be below five minutes, which would make stroke triage in the ambulance by EEG logistically feasible

Study objective

To develop and validate an algorithm based on dry electrode cap EEG data that accurately determines the likelihood of an LVO-a in patients with a suspected AIS in the ER.

Study design

Validation of several existing algorithms and development of one or more new algorithms; selection of algorithm with best diagnostic accuracy for validation.

Study burden and risks

There are no risks or benefits for patients in this trial involved.

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 (18> years old) presented at the ED with suspect stroke.

Exclusion criteria

Suspected sars-cov-2 infection, open headwound or acute infection of the scalp.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-08-2021
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	electroencephalography
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	15-02-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL75474.018.20