Clinical evaluation of pre-hospital stroke triage devices- Electroencephalography

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Primary objective: 1. To validate the data quality and diagnostic accuracy of StrokePointer to detect LVO stroke among patients with a suspected stroke in the pre-hospital setting.
Secondary objectives:1. To determine the user-friendliness of...

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

Summary

ID

NL-OMON57286

Source
ToetsingOnline

Brief title
CROSSROADS-EEG

Condition

- Central nervous system vascular disorders
- Embolism and thrombosis

Synonym
cerebrovasculair accident, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Hartstichting

Intervention

Keyword: Electroencephalography, Large vessel occlusion, Pre-hospital triage, Stroke

Outcome measures

Primary outcome

- Proportion of patients with a technically successful EEG dataset

- Based on the EEG data and using the final diagnosis established by an adjudication committee as the gold standard we will calculate diagnostic accuracy of StrokePointer for LVO stroke of the anterior circulation among patients with a suspected stroke, as measured with AUC as well as sensitivity and specificity.

Secondary outcome

- User-friendliness rating of StrokePointer by ambulance personnel, ER personnel and researchers.

- Safety assessment of StrokePointer.

Study description

Background summary

Endovascular thrombectomy (EVT) is the standard treatment for large vessel occlusion (LVO) stroke. However, EVT can only be performed in specialized hospitals and its effect on functional outcome rapidly decreases with passing time (time = brain). Since ambulance personnel cannot determine whether a patient has a stroke that is eligible for EVT, 54% of patients with an LVO stroke are primarily presented at a non-EVT capable hospital. These patients then require interhospital transfer, resulting in average delay in time-to-EVT of 1 hour in the Netherlands. Therefore, providing ambulance personnel with tools to identify patients with a possible LVO stroke in the ambulance, allowing direct transport to an EVT capable hospital, is much needed. Dry electrode electroencephalography (EEG) has shown to have a high diagnostic accuracy for LVO stroke detection among patients with a suspected stroke (area

under the receiving operating curve [AUC]: 0.91). However, in 32% of patients EEG signal quality was too poor to analyse. A new portable EEG-based triage device (StrokePointer) has been developed by TrianecT with the aim to collect and analyse EEG data in patients suspected of acute stroke. In this study, we intend to validate the safety and effectiveness of the device.

Study objective

Primary objective:
1. To validate the data quality and diagnostic accuracy of StrokePointer to detect LVO stroke among patients with a suspected stroke in the pre-hospital setting.

Secondary objectives:
1. To determine the user-friendliness of StrokePointer according to ambulance personnel.
2. To determine safety performance of StrokePointer.
3. Diagnostic accuracy and data quality for LVO stroke within the following subgroups: sex (men vs. women) and age (above vs. below 60).
4. Discriminative power of StrokePointer for ischemic stroke vs. stroke mimic.

Study design

CROSSROADS-EEG is an investigator-initiated, prospective, multi-centre cohort study.

Study burden and risks

A single EEG recording will be performed in each patient. An EEG recording is a safe and non-invasive procedure, regularly performed in standard medical practice. The use of dry electrodes makes it possible to perform the measurement in less than five minutes and cause no to minimal delay. We expect no health risks. The treating physicians and the ambulance personnel will not interpret the EEG recording, therefore the EEG results will not influence choices regarding diagnosis, treatment or the hospital to which the patient is presented. Deferred informed consent will be asked, and if informed consent is given, a case report form (CRF) will be filled out containing information on patient characteristics, medical history, medication use, physical and neurological examination performed by the treating physician, results of imaging studies, diagnosis and treatment as well as logistical and technical information, obtained from the patient, the treating physician and the Emergency Medical Service (EMS). There are no follow up visits. For the patient, there is no benefit of participation in the study.

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

- Suspected acute ischemic stroke as per judgement by the ambulance personnel.
- Age 18 years or older
- Onset of symptoms (or last seen well) <24 hours
- Written informed consent by patient or legal representative (deferred)

Exclusion criteria

- Injuries or infections of the scalp in the area of the electrode cap placement

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	325
Type:	Anticipated

Medical products/devices used

Generic name:	StrokePointer
Registration:	No

Ethics review

Approved WMO

Date:	27-01-2025
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	NL85665.000.23