Eletroencephalography for the triage of stroke patients in the ambulance.

No registrations found.

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

Summary

ID

NL-OMON20036

Source
Nationaal Trial Register

Brief title
EEG4STROKE

Health condition

Acute ischemic stroke

Sponsors and support

Primary sponsor: Amsterdam University Medical Centers, location AMC
Source(s) of monetary or material Support: EUROSTARS

Intervention

Outcome measures

Primary outcome

Co-primary end points: sensitivity and specificity of EEG for diagnosis of LVO-a in suspected AIS patients;

Secondary outcome

Developing novel algorithms with optimal diagnostic accuracy for LVO-a detection with EEG;
Positive predictive value (PPV) and negative predictive value (NPV) of EEG for diagnosis of LVO-a in suspected AIS patients;
Technical and logistical feasibility of performing EEGs on patients with a suspected AIS;

Study description

Background summary

Stroke is a sudden interruption in the blood supply of the brain. Stroke is the most frequent cause of long-term disability and the third most frequent cause of death in developed countries. Because of the aging population in Europe, annual incidence of stroke is expected to increase from 1.1 million in 2000 to 1.5 million in 2025. In 2015 care for stroke patients worldwide underwent a revolution with the introduction of a new therapy; endovascular thrombectomy (EVT). EVT is now 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 can be performed in selected hospitals only. Currently, approximately half of EVT eligible patients are initially admitted to hospitals that do not provide this therapy. 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. 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

The goal of EEG4STROKE is to test a device that enables paramedics to accurately diagnose patients with suspected stroke on site (in the ambulance or living room of the patient). EEG4STROKE will integrate hardware and software to triage stroke patients. Early triage enables earlier hospital selection and faster treatment, which will drastically improve patient’s chance of recovery.

Study design

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Intervention

EEG

Contacts

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Eligibility criteria

Inclusion criteria

- Suspected acute ischemic stroke, as judged by the paramedic presenting the patient to the ER or known AIS with an LVO-a;
- Onset of symptoms or, if onset was not witnessed, last seen well <24 hours ago;
- Age of 18 years or older;
- Written informed consent by patient or legal representative (deferred).

Exclusion criteria

- Injury or active infection of electrode cap placement area;
- SARS-COV-2 infection (confirmed or suspected).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-08-2021
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9765
Other	METC AMC : METC2020_304

Study results