Algorithm development through artificial intelligence for the triage of stroke patients in the ambulance with electroencephalography

Published: 15-06-2021
Last updated: 05-04-2024

To develop one or more novel AI-based algorithms with optimal diagnostic accuracy for identification of LVO stroke in patients with a suspected AIS in the prehospital setting, based on ambulant EEG data.

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

Summary

ID

NL-OMON52101

Source
ToetsingOnline

Brief title
AI-STROKE

Condition

- Central nervous system vascular disorders

Synonym
cerebral infarction, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Eemagine GmbH: in kind ¤80,2k; in cash ¤10k,Health Holland - Amsterdam UMC TKI-PPP Grant,Nico.lab B.V.: in kind ¤65,1k; in cash ¤61,8k

Intervention

Keyword: Artificial intelligence, EEG, Stroke, Triage

Outcome measures

Primary outcome

Based on the EEG data, and using the final diagnosis established by an adjudication committee as the gold standard, one or more novel AI-based EEG algorithms will be developed with maximal diagnostic accuracy to identify patients with an LVO stroke of the anterior circulation in a population of patients with suspected AIS.

Secondary outcome

- AUC, sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of the AI-STROKE algorithms based on ambulant EEG for diagnosis of LVO of the anterior circulation in suspected AIS patients in the prehospital setting;

- AUC, sensitivity, specificity, PPV and NPV of existing EEG algorithms based on ambulant EEG for diagnosis of LVO of the anterior circulation in suspected AIS patients in the prehospital setting;

- AUC, sensitivity, specificity, PPV and NPV of existing and newly developed EEG algorithms based on ambulant EEG for detection of LVO stroke of the posterior circulation, intracerebral hemorrhage, transient ischemic attack, and stroke mimics;

- Technical and logistical feasibility (e.g. in terms of EEG channel

reliability) of paramedics performing ambulant EEG in patients with a suspected

AIS in the prehospital setting;

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). Because of its complexitiy, EVT is performed in selected hospitals only. Currently, approximately half of the EVT-eligible patients are initially admitted to hospitals that do not provide this therapy. This delays initiation of treatment by approximately one hour, which decreases the chance of a good functional outcome. Direct presentation of all patients with a suspected AIS to EVT-capable hospitals is not feasible, as only circa 7% of these patients are eligible for EVT. Therefore, an advanced triage method that reliably identifies patients with an LVO in the pre-hospital setting is necessary.
Previous studies have shown almost immediate changes in the EEG signal in response to reduction of the cerebral blood flow. Furthermore, differences between the EEG-signal of patients with an LVO and all other suspected stroke patients have been found. Results from our pilot ELECTRA-STROKE study (NL65939.018.18) suggest that, by using dry electrodes, an EEG registration can be performed in the pre-hospital setting by relatively unexperienced ambulance paramedics, within five minutes. A next crucial step is to develop an EEG-based algorithm that accurately and reliably identifies patients with an LVO and gives an easy to interpret binary outcome: LVO or no LVO.

Study objective

To develop one or more novel AI-based algorithms with optimal diagnostic accuracy for identification of LVO stroke in patients with a suspected AIS in the prehospital setting, based on ambulant EEG data.

Study design

AI-STROKE is an investigator-initiated, multicenter, diagnostic test study.

Part A: Algorithm development and validation in patients with suspected stroke in the prehospital setting. Furthermore, analysis of the technical and logistical feasibility of ambulance paramedics performing EEG registrations in the pre-hospital setting in suspected stroke patients.

Part B: Algorithm development and validation in patients with suspected stroke

in the emergency room.

Study burden and risks

A single EEG will be performed in each patient. An EEG-measurement 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. Initiation of stroke treatment will therefore not be delayed. The dry electrodes will cause no to minimal discomfort, and only during the measurement. We expect no health risks, since we will use only CE marked products for performing the EEG. The treating physicians and the ambulance paramedics are not trained nor instructed to interpret the EEG, therefore the EEG results will not influence choices regarding diagnosis or treatment. Deferred informed consent will be asked as soon as feasible, preferably within 72 hours after arrival at the hospital or at discharge (whichever comes first). 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, technical and usability 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 assessed by the attending ambulance paramedic, or patients with a known LVO stroke who are transferred for EVT;
- Onset of symptoms or, if onset not witnessed, last seen well <24 hours ago;
- Age of 18 years or older;
- Written informed consent by patient or legal representative.

Exclusion criteria

- Injury or active infection of electrode cap placement area.
- Suspected COVID-19 infection.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-06-2022
Enrollment:	1192

Type:	Actual

Medical products/devices used

Generic name:	Waveguard touch dry electrode cap (class I) and eego amplifier (class IIa)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-06-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-05-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-07-2022
Application type:	Amendment
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	NL75429.018.22