# Ultrafast diagnosis of epilepsy: a randomised controlled trial of AI-assisted interpretation of ambulatory EEG recordings versus routine care.

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To evaluate the effect of AI-assisted interpretation of ambulatory EEG recordings compared to standard care (starting with a routine EEG) on the time to diagnose epilepsy (measured as the time in weeks between initial referral for an EEG and the...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Seizures (incl subtypes) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON56882

**Source**
ToetsingOnline

**Brief title**
Epilepsy assessment by AI supported EEG

### Condition

- Seizures (incl subtypes)

**Synonym**
Epilepsy

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Medisch Spectrum Twente

**Source(s) of monetary or material Support:** Dit onderzoek is eigen-geïnitieerd. De aanstelling van de coördinerend onderzoeker wordt gefinancierd door de Reggeborgh Foundation;door middel van het Reggeborgh Research Fellowship. Binnen dit fellowship wordt dit onderzoek uitgevoerd;echter is het bedrijf geen opdrachtgever voor dit onderzoek.

## Intervention

**Keyword:** artificial intelligence, EASE, EEG, epilepsy

## Outcome measures

### Primary outcome

The main study parameter is the time-to-diagnosis, defined as the time (in

weeks) from initial referral to final diagnosis of epilepsy.

### Secondary outcome

- Total cost of each study arm.

- Time spend by medical professionals reviewing the EEGs.

- Sensitivity, specificity and F1 score of routine EEG and ambulatory EEG with

AI.

- Patient satisfaction score measured by the patient satisfaction questionnaire.

- Time patients invested in the diagnostic process of both study arms.

# Study description

### Background summary

Diagnosis of epilepsy is not straightforward; many epilepsy patients receive their diagnosis years after their first symptoms. Current standard of care for the diagnosis of epilepsy generally includes a routine electroencephalogram (EEG). This EEG is visually inspected for signatures of epilepsy: interictal epileptiform discharges (IEDs). These are short, characteristic, transient anomalies in the EEG, associated with an increased likelihood of seizures. The sensitivity of a routine EEG is low, however, due to the short duration of the recording. Furthermore, IEDs occur more frequently during sleep than during wakefulness, whereas routine EEGs are performed while the patient is awake.

After a normal or inconclusive routine EEG, a second routine EEG, a sleep-deprivation EEG or a 24-hour ambulatory EEG may be considered. As an ambulatory EEG has a longer duration and captures EEG data during sleep, it greatly improves the sensitivity for IED capture. Although it is generally accepted that ambulatory recordings are highly valuable for diagnostics in epilepsy, they are not routinely used in most hospitals due to the time consuming nature of ambulatory EEG interpretation that takes 2-3 hours for review. Our group recently developed an artificial intelligence (AI) algorithm for IED detection. This algorithm performs on par with experts and realizes a 50- to 75-fold time reduction to analyse ambulatory EEG. We hypothesize that using AI-assisted interpretation of ambulatory EEG recordings is more efficient in comparison to the current clinical practice (starting with a routine EEG) to diagnose epilepsy and will significantly reduce the time to diagnosis in patients referred for possible epilepsy.

## Study objective

To evaluate the effect of AI-assisted interpretation of ambulatory EEG recordings compared to standard care (starting with a routine EEG) on the time to diagnose epilepsy (measured as the time in weeks between initial referral for an EEG and the final diagnose).

## Study design

Randomized controlled trial.

## Intervention

Patients are randomized into two treatment arms: the standard care arm and the ultra-fast AI arm. In the ultra-fast AI arm, an ambulant EEG recording is performed and analyzed by an artificial intelligence algorithm. This algorithm highlights events in the EEG with a high suspicion of interictal epileptiform abnormalities. These marked events are visually assessed by a clinical neurophysiologist. In addition, at least 20 minutes of the ambulatory EEG will be visually assessed (similar to that in the standard care arm). The clinical neurophysiologist will give the final conclusion.

## Study burden and risks

Participants will be randomized to one of the study arms, the standard care or the ultrafast diagnostics arm. Participants in the ultrafast diagnostics arm will undergo a 24-hour routine EEG. The first 20 minutes of the ambulatory EEG will be visually similar to standard care. In addition, the complete EEG will be reviewed with a hybrid approach; in which the complete EEG is analysed by the AI algorithm and all detected events are shown to an expert. Patients in both study arms will have one extra outpatient clinic appointment after 1 year

to follow-up on their diagnosis. If the ultrafast diagnosis arm is proven to reduce time-to-diagnosis significantly this will greatly impact future care. Patients will receive their diagnosis sooner, which allows for earlier treatment. Therefore, the (limited) risks and burden for the participating capacitated adults are in proportion with the potential value of this 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

- The participant must be an adult (>=18 years).
- The participant is referred for a routine EEG with the differential diagnosis of epilepsy.

### Exclusion criteria

- Patients with cognitive impairments that limits patients* understanding of the research purpose and to give informed consent.
- Patients who previously have been diagnosed with epilepsy.

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Diagnostic

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 03-10-2024 |
| Enrollment: | 62 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | Ultrafast interictal epileptiform discharges detection algorithm |
| Registration: | No |

## Ethics review

Approved WMO

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| Date: | 12-07-2024 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# 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 | NL86811.100.24 |