

Seizure alarm with wearable electrocardiogram device for people with epilepsy

Submission date 14/08/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/08/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/01/2025	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The main aim of this study is to create a wearable seizure alarm which can detect epileptic seizures. Recent studies have shown that heart rate variability analysis measured with an electrocardiogram (ECG) can detect seizures in patients with epilepsy. Therefore, this study will develop an online detection of epileptic seizures using small, wearable and wireless ECG devices. The study will assess the detection of seizures using a wearable ECG patch, which sends ECG data to a smartphone with implemented real-time seizure detection algorithms, during long-term video-EEG monitoring.

Who can participate?

Patients above the age of 3 years and with a diagnosis of probable focal or generalized epilepsy, enrolled for long-term video/EEG monitoring at Aarhus University Hospital or the Danish Epilepsy Center

What does the study involve?

The participants will wear the ECG device during their 1-5 days of term video/EEG monitoring and will respond to the seizure detection app on a smartphone.

What are the possible benefits and risks of participating?

If and when commercialized the wearable seizure alarm will be a vital asset for patients enabling caregivers and families to take necessary precautions during seizures and obtain an objective seizure count to optimize treatment. Side effects of temporary skin irritation may occur at the location of the ECG electrodes.

Where is the study run from?

Aarhus University Hospital (Denmark)

When is the study starting and how long is it expected to run for?

August 2021 to December 2024

Who is funding the study?

Danish Council for Independent Research (Denmark)

Who is the main contact?

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Contact information

Type(s)

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

DFF Sagsnummer: 0134-00400B

Study information

Scientific Title

Seizure alarm with wearable electrocardiogram device for people with epilepsy: a Phase III study

Study objectives

The overall aim of this study is to investigate if an implementation of a heart rate variability (HRV)-based seizure detection algorithm into small, wearable ECG devices, is reliable as a seizure alarm system.

The hypotheses are:

Heart rate variability algorithms implemented into a small, non-invasive, wearable and wireless ECG device can reliably detect seizures in real-time, and send seizure alarms.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 13/01/2022, Medical Research Ethics Committees (Ørestads Boulevard 5, København S, 2300, Denmark; +45 (0)72 21 66 77; dketik@dketik.dk), ref: Sagsnr: 2119788

Study design

Multicenter Phase III clinical trial

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Other, Efficacy

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Epilepsy

Interventions

The recording and data collection will be done using the portable ECG device, C3 Holter Monitor patch. The patients will be recorded during the whole 1-5 day period they are enrolled for video-EEG long-term monitoring (LTM). During the enrolment period, patients will complete a

standardized training session (exercise bike) to obtain a control period, as HRV has been proven to change with physical exercise. Furthermore, the patients will be asked to perform an algorithmic stress test, as cognitive stress is known to influence sudden changes in the HRV parameters.

Statistical analysis of the sensitivity and specificity (false positive alarms) of seizure detection by means of the HRV algorithm developed in a previous study (Jeppesen et al., Epilepsia 2019) will be conducted for the whole enrollment period of 1-5 days (inclusive the exercise and stress test). This will be done both individually and group-specifically (epilepsy form and type).

The applicability and usability of the mobile seizure detection application and device will be evaluated. Significant HRV differences between frontal lobe and temporal lobe epilepsy will be identified. The seizure detection app will log all seizure alarms and register patient responses to the alarms.

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Phase III

Drug/device/biological/vaccine name(s)

C3 Holter Monitor patch

Primary outcome measure

Seizure detection sensitivity and false alarm rate using the wearable ECG device in connection with the seizure detection app for patients with marked autonomic changes during seizures who are enrolled in a 1-5 days long-term video-EEG monitoring

Secondary outcome measures

1. Seizure detection sensitivity and false alarm rate using the wearable ECG device in connection with the seizure detection app for patients without marked autonomic changes during seizures who are enrolled in a 1-5 days long-term video-EEG monitoring
2. Sensitivity of specific seizure types (focal and generalized seizures) of the wearable ECG device in connection with the seizure detection app for the enrolled patients in the 1-5 days long-term video-EEG monitoring study
3. Applicability and usability of the mobile seizure detection application and device of the enrolled patients in the 1-5 days long-term video-EEG monitoring study, assessed using side effects (e.g. skin irritation), dropout rates and reasons for dropouts

Overall study start date

01/08/2021

Completion date

01/12/2024

Eligibility

Key inclusion criteria

1. Patients enrolled for long-term video/EEG monitoring at Aarhus University Hospital or Danish Epilepsy Center
2. Above the age of 3 years
4. Diagnosis of probable focal or generalized epilepsy

Participant type(s)

Patient

Age group

Mixed

Lower age limit

4 Years

Sex

Both

Target number of participants

100-120

Key exclusion criteria

1. Pregnant women will be excluded from the study due to foreseeable noise on the ECG recording
2. Incompetent adults

Date of first enrolment

07/02/2022

Date of final enrolment

01/11/2024

Locations**Countries of recruitment**

Denmark

Study participating centre

Aarhus University Hospital

Department of Neurology

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Study participating centre

Danish Epilepsy Center

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Organisation

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Sponsor type

University/education

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ROR

<https://ror.org/01aj84f44>

Funder(s)

Funder type

Government

Funder Name

Danmarks Frie Forskningsfond

Alternative Name(s)

Danish Council for Independent Research, Det Frie Forskningsrad, Independent Research Fund
Denmark, DFF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Denmark

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

01/03/2025

Individual participant data (IPD) sharing plan

The dataset generated during and/or analysed during the current study are not expected to be made available due to the approval limitations by the ethical committee

IPD sharing plan summary

Not expected to be made available