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Seizure alarm with wearable electrocardiogram device for people with epilepsy

Submission date
14/08/2024

Recruitment status
No longer recruiting

Registration date
21/08/2024

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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?
1. Assistant Professor Jesper Jeppesen, jespjepp@rm.dk
2. Professor Sándor Beniczky, sandor.beniczky@clin.au.dk

Contact information

Type(s)
Principal investigator

Contact name
Prof Sándor Beniczky

ORCID ID
https://orcid.org/0000-0002-6035-6581

Contact details
Palle Juul-Jensens Boulevard 165, plan 2, krydspunkt J209
Århus N
Denmark
8200
+45 (0)22888925
sandor.beniczky@clin.au.dk

Type(s)
Public, Scientific

Contact name
Dr Jesper Jeppesen

ORCID ID
https://orcid.org/0000-0002-3095-2040

Contact details
Palle Juul-Jensens Boulevard 165, plan 2, krydspunkt J209
Århus N
Denmark
8200
+45 (0)22888925
jespjepp@rm.dk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Other, Efficacy

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

Phase
Phase III

Drug/device/biological/vaccine name(s)
C3 Holter Monitor patch

Primary outcome(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
4 years

Sex
All

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
Palle Juul-Jensens Boulevard 165, plan 2, krydspunkt J209
Århus N
Denmark
8200

Study participating centre
Danish Epilepsy Center
Kolonivej 1
Dianalund
Denmark
4293

Sponsor information

Organisation
Aarhus University

ROR
https://ror.org/01aj84f44

Funder(s)

Funder type
Government

Funder Name
Danmarks Frie Forskningsfond

Alternative Name(s)
Danish Council for Independent Research, Independent Research Fund Denmark, Det Frie Forskningsrad, DK Frie Forsk.fond, DFF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Denmark

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes