Prospective seizure prediction in epileptic patients using VOC analysis by electronic nose (pilot)

Published: 30-11-2020
Last updated: 09-04-2024

We hypothesize that VOC analysis by eNose is able to detect intra-individual changes in exhaled breath profiles and body odors of epilepsy patients prior to a seizure.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Seizures (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON55086

Source
ToetsingOnline

Brief title
EPIC study

Condition

- Seizures (incl subtypes)

Synonym
convulsions, epileptic seizures

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Epilepsie Instellingen Nederland
Source(s) of monetary or material Support: New Life Wearables,Stichting Epilepsie Instellingen Nederland (SEIN)

Intervention

Keyword: Electronic Nose, Epilepsy, Seizures

Outcome measures

Primary outcome

To determine the diagnostic accuracy, including an ROC curve, sensitivity and specificity, of exhaled breath analysis by eNose for seizure detection and prediction in epileptic patients.

To determine the diagnostic accuracy of body odor analysis by eNose for seizure detection and prediction in epileptic patients.

Secondary outcome

To determine the diagnostic accuracy of exhaled breath and body odor analysis by eNose for the discrimination between different types of seizures.

To compare intra-individual temporal fluctuations in VOC profiles in interictal, pre-ictal, ictal and postictal state.

Study description

Background summary

The unpredictability of seizures has a major impact on the quality of life of epileptic patients as it often leads to injuries and limits performing ordinary daily tasks and jobs. Over the past decades, efforts are ongoing to develop devices that could detect and predict seizures that could be used in daily lives of the patients. These devices could potentially prevent accidents and improve outcomes by allowing early intervention.
Recent advances in the field of metabolomics have resulted in the development of electronic noses (eNose) that are based on an array of sensors reacting to the complete mixtures of volatile organic compounds (VOCs) in exhaled breath. In a small pilot study, we were able to discriminate patients with epilepsy in interictal state from healthy individuals based on the mixture of VOCs measured

in their exhaled breath.

Study objective

We hypothesize that VOC analysis by eNose is able to detect intra-individual changes in exhaled breath profiles and body odors of epilepsy patients prior to a seizure.

Study design

Single-centre pilot study with an observational cohort study design.

Study burden and risks

As this concerns observational research, no direct risk is involved with participation in this study. Participation in this study does not affect the subjects* regular care.

Contacts

Public
Stichting Epilepsie Instellingen Nederland

Achterweg 2
Heemstede 2103 SW
NL
Scientific
Stichting Epilepsie Instellingen Nederland

Achterweg 2
Heemstede 2103 SW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

>= 18 years of age
Admitted to SEIN for video-EEG recording
Diagnosed with epilepsy
High seizure frequency (1 or more per week), or admitted for multiple days of video-EEG as part of epilepsy surgery track with tapering of anti-seizure medication
Mentally competent and with no learning disabilities

Exclusion criteria

Recent (< 12 hours) intake of alcohol
Psychogenic Nonepileptic Seizures (PNES), without comorbidity of epilepsy or with high level of doubt of epilepsy diagnosis
Unwillingness or inability to comply with the study protocol for any other reason

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-05-2021
Enrollment:	10

Type:	Actual

Medical products/devices used

Generic name:	eNose
Registration:	No

Ethics review

Approved WMO Date:	30-11-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	04-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL73338.058.20

Study results

Date completed: 28-11-2022

Actual enrolment: 4

Summary results

Trial is onging in other countries