# The 'Livassured' Combined Sensor system to detect Epileptic Noctural SEizures (LICSENSE)

Published: 01-09-2014
Last updated: 20-04-2024

The primary objective of this trial are to assess the clinical usefulness (in terms of sensitivity and positive predictive value of 1. Combined heart rate and movement detection2. And the added value of video and audio detection in a population of...

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

## Summary

### ID

NL-OMON44973

**Source**
ToetsingOnline

**Brief title**
LICSENSE trial

### Condition

- Seizures (incl subtypes)

**Synonym**
Epilepsy

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Epilepsiecentrum Kempenhaeghe
**Source(s) of monetary or material Support:** NutsOhra;ZonMW

## Intervention

**Keyword:** Accelerometry, Audio analysis, Epilepsy, Heart rate, Seizure detection, Video analysis

## Outcome measures

### Primary outcome

The combined analysis of heart rate and accelerometry, the added value of

video/audio analysis and the technical performance are primary endpoints.

### Secondary outcome

Secondary end points are the performances of heart rate, accelerometry, video

and audio alone, comparison with the Emfit bed sensor, quality of life,

optimalisation of care and levels of trust of caregivers in system performance.

# Study description

### Background summary

Seizure detection is important in the care of epilepsy patients with a mental impairment and children with severe epilepsy for the following reasons
- these patients often do not report seizures by themselves
- current alarm systems based on audio severely underreport seizures
- seizures in these often refractory patients may require acute intervention, medication in case of seizure clusters, may lead to status epilepticus and cardiopulmonary instability, a risk for SUDEP (sudden unexplained death in epilepsy).
- seizures can result in other complications (falls, headache, *hang-over* fatigue, inability to work) that can be prevented by early detection.
- accurate knowledge of seizure frequency is necessary to adjust anti-epileptic drugs
- seizure detection may enhance the feeling of safety of caregivers and parents and improve their sleep and quality of life.
Although increasingly reliable bed-sensors become available there is still a need for further improvement of seizure detection devices.
We developed a seizure detection device for home monitoring of these seizures during the night. This is a multimodal device which automatically analyses

heart rate, accelerometry, video and audio signals.

### Study objective

The primary objective of this trial are to assess the clinical usefulness (in terms of sensitivity and positive predictive value of
1. Combined heart rate and movement detection
2. And the added value of video and audio detection in a population of adult patients with mental impairment and children from 2 -18 years of age with severe refractory epilepsy
And the feasibility and technical performance of the sensor system
This will be done in and intention-to-diagnose set-up that includes the risk of technical failure

Secondary objectives of this trial are quality of life and trust of caregivers (value sensitive design list). The performances of the individual modalities (heart rate, accelerometry, video audio), comparison with the Emfit bed sensor.

### Study design

This is a non-randomized observational clinical trial in 30 children of 2-18 years of age and mentally impaired subjects with medically intractable epilepsy. Each subject will undergo all-night monitoring during 3 months in which the multimodal seizure detection system will be applied in the home situation of the patient. Expert review of the nocturnal video recordings will serve as a gold standard. Seizures will be stratified according to type and severity.

### Study burden and risks

There are no risks and there is no burden associated with participation in the study.

## Contacts

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**Scientific**
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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

## Inclusion criteria

Subjects who meet all of the following criteria are eligible for this trial:
1. Between 2 and 18 years of age with or without mental impairment, or between 18 - 65 years with a mental impairment.
2. Major motor seizures defined as tonic-clonic, generalized tonic, hypermotor or series of myoclonic seizures.
3. Minimal nocturnal seizure frequency: 1/month.
4. The mentally impaired patients all live in the long-term facilities at Kempenhaeghe or SEIN. Children may live in their family home.
5. Informed consent form signed by legal representatives.

## Exclusion criteria

Subjects meeting one or more of the following criteria cannot be selected:
1. Intensive non-epileptic movement patterns such as severe choreatiform movements due to birth defects, intensive sleep walking, frequent night terrors (> 1/night)
2. Only minor motor seizures: non-generalised or short (< 10 sec.) tonic seizures or isolated myoclonias.
3. Pacemaker
4. Inability to comply to the trial procedure
5 Dark colored skin.

# Study design

## Design

**Study type:** Observational non invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 13-01-2015 |
| Enrollment: | 51 |
| Type: | Actual |

# Ethics review

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|---|---|
| Approved WMO Date: | 02-09-2014 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 08-12-2015 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 06-10-2016 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 19-01-2017 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

# 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 | NL47654.041.14 |