Leg Epilepsy Guard Study - LEGS

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The purpose of this study is to determine whether a NightWatch worn on the leg detects the same seizures as a NightWatch worn on the arm. In addition, the signal quality of both devices will be examined.

Ethical review	Approved WMO
Status	Pending
Health condition type	Seizures (incl subtypes)
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON57506

Source
Onderzoeksportaal

Brief title
Leg Epilepsy Guard Study (LEGS)

Condition

- Seizures (incl subtypes)

Synonym
Epilepsy

Research involving
Human

Sponsors and support

Primary sponsor: Kempenhaeghe
Source(s) of monetary or material Support: ZonMw

Intervention

- Medical device

Explanation

N.a.

Outcome measures

Primary outcome

The primary outcome measure of this study is whether the NightWatch on the leg detects the same seizures as the NightWatch on the arm.

Secondary outcome

Secondary outcome measures are the quality of heart rate data, amount of time the device records being in “rest state,” and which algorithm has triggered alarm.

Study description

Background summary

Having major, epileptic seizures during the night can pose great risks. Therefore, it is important to detect these seizures so that a caregiver can be alerted. NightWatch is a seizure detection device that has been extensively scientifically tested for detecting seizures on the arm. In some cases, however, there is a preference for wearing NightWatch on the leg. There is currently no scientific evidence for the effectiveness of NightWatch on the leg.

Study objective

The purpose of this study is to determine whether a NightWatch worn on the leg detects the same seizures as a NightWatch worn on the arm. In addition, the signal quality of both devices will be examined.

Study design

This study is designed as an intervention study in which participants will temporarily wear a second NightWatch around their leg.

Intervention

Participants will wear a second NightWatch worn around their leg for 4 weeks.

Study burden and risks

Participation in this study carries no specific risks, and the additional strain is minimal. Participants will wear an extra NightWatch around the leg for 4 weeks, but they are already used to sleeping with a NightWatch every night. In addition, participants are asked to complete a short questionnaire about their experience using a NightWatch around the leg. Also, participants are asked to record whether alarms from the NightWatch worn around the arm were true or false positives.

When researching the functionality of NightWatch around the leg, it is important to look at the entire target population that is currently using the NightWatch and for which it has been validated. Since the NightWatch has been clinically validated for children aged 4 years and older (Lazeron et al., 2022; van Westrhenen et al., 2023), and is widely used at home in children with seizures, it is highly relevant to include this group in this study. These are children who are already used to sleeping with a NightWatch around the arm every night, so it is expected that the temporary addition of a second module is only a minimal burden. If sleeping with a second module around the leg does prove to be too stressful for a child, parents will be instructed by the researchers to stop participation in the study.

Contacts

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Trial sites

Trial sites in the Netherlands

Epilepsiecentrum Kempenhaeghe, Heeze
Target size: 20

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. At least 1 major nocturnal seizure per week
2. Already uses a NightWatch on the arm linked to the internet
3. Living in the Netherlands
4. At least 4 years old

Exclusion criteria

Unwilling to wear a second NightWatch around the leg

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Efficacy/Effectiveness

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-04-2025
Enrollment:	20
Duration:	1 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	Medical device
Generic name:	NightWatch
Registration:	Yes - CE intended use

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO

Date:	14-04-2025
Application type:	First submission
Review commission:	METC MMC

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
Research portal	NL-009494