# In-home EEG monitoring in suspected epilepsy.

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As an alternative to the routine diagnostics, we propose long-term (24-48h) in-home EEG recordings for patients evaluated for epilepsy, assisted by computer analysis of the EEG. We expect that long-term in-home EEG monitoring early in the diagnostic...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

# Samenvatting

#### ID

NL-OMON28676

Bron NTR

#### Aandoening

The routine diagnostics and the new approach, 24-48h in-home EEG monitoring, will be studied in patients evaluated for epilepsy.

#### Ondersteuning

Primaire sponsor: M.J.A.M. van Putten MD PhD
Medisch Spectrum Twente
Afdeling Klinische Neurofysiologie
Overige ondersteuning: High Tech Health Farm; subsidie verstrekt door provincie
Overijssel

## **Onderzoeksproduct en/of interventie**

#### Uitkomstmaten

#### Primaire uitkomstmaten

Diagnostic accuracy of the 24-48h in-home EEG monitoring procedure in epilepsy, in terms of

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# **Toelichting onderzoek**

#### Achtergrond van het onderzoek

Conventionally, a patient that experienced a seizure visits a neurologist, after which an EEG is recorded for 20-30 minutes by a lab-technician. Such a routine EEG has relatively low sensitivity in epilepsy, ranging between 25-56%. This low sensitivity typically results in additional EEG recordings, often after sleep deprivation to evoke epileptiform activity in the EEG. This typically requires an additional visit to the hospital for the recording procedure, and a third visit to the treating neurologist.

This "routine procedure", including both routine and sleep records, results in a sensitivity of approximately 70-80% and is relatively time-consuming (over a period of several weeks), both for the patient and the treating physician. Furthermore, misclassification is still common, ranging from 5-23%. The main reason for the limited sensitivity of the standard diagnostic strategy is the relatively short recording time, as in many patients with epilepsy 20-30 min. EEG recordings do not show any abnormality.

As an alternative, we propose routine long-term (24-48h) EEG recordings for patients evaluated for epilepsy. Long-term EEG monitoring early in the diagnostic process of epilepsy will most likely shorten the time-to-diagnosis and enhance diagnostic accuracy.

In this study, we will evaluate the use of 24-48h ambulatory in-home EEG monitoring early in the diagnostic process after a first seizure, as compared to the routine procedure. We will also evaluate the use of automated EEG analysis, as visual analysis of long-term EEG recordings is a very time-consuming procedure.

#### Doel van het onderzoek

As an alternative to the routine diagnostics, we propose long-term (24-48h) in-home EEG recordings for patients evaluated for epilepsy, assisted by computer analysis of the EEG. We expect that long-term in-home EEG monitoring early in the diagnostic process of epilepsy will shorten the time-to-diagnosis, reduce the number of hospital visits and related costs, and enhance diagnostic accuracy.

#### Onderzoeksopzet

Diagnostic accuracy of the in-home EEG monitoring procedure in epilepsy will be expressed through its sensitivity and specificity. These parameters will be assessed using each patient's diagnosis (whether he/she has epilepsy or not) and test results (whether there are epileptiform discharges in the EEG or not). The same parameters will also be determined in the control group following the routine procedure, after which the accuracy of both procedures will be compared. The number of hospital visits, time-to-diagnosis and related costs will be evaluated in both the 'routine' and the 'in-home' group. The number of hospital visits and the time-to-diagnosis (in days) will be obtained via patient data files and database and include all visits (e.g. consultations, EEG-recordings) that were made for diagnostic purposes from first visit to diagnosis. Direct costs related to the diagnostic process include costs for e.g. consultations, EEG recordings, personnel costs, depreciation of the equipment. Indirect costs include costs for travelling to the hospital and for taking off from work, and will be estimated via a questionnaire that must be filled out by the patient after diagnosis and can be found as an attachment to this protocol.

The remaining two parameters will additionally be evaluated in the 'in-home' group. In a pilot study, usability will be pre-evaluated by exploratory means, e.g., we will study how to optimize signal quality, electrode configuration, and amplifier settings. User experience will be pre-evaluated by means of a questionnaire. Both aspects (usability and user experience) will also be evaluated in the actual trial by the same means.

Accuracy of computer algorithms in detecting epileptiform discharges in the EEG will be measured in terms of their sensitivity and specificity, where the 'gold standard' is the neurologist's assessment of the EEG by visual analysis.

#### **Onderzoeksproduct en/of interventie**

Suspected epilepsy patients will be randomly assigned to either the routine EEG procedure or the in-home EEG procedure (intervention group).

# Contactpersonen

#### **Publiek**

[default] The Netherlands

#### Wetenschappelijk

[default] The Netherlands

# **Deelname eisen**

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 1. Seeing neurologist for suspected epilepsy after first insult;
- 2. Age above 18 years;
- 3. No previous history of epilepsy.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients who have any experience with the current routine EEG procedure in epilepsy diagnosis will be excluded from participation.

# Onderzoeksopzet

#### Opzet

Туре:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

#### Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-05-2011
Aantal proefpersonen:	50
Туре:	Verwachte startdatum

# **Ethische beoordeling**

Positief advies

Datum:	
Soort:	

# Registraties

## **Opgevolgd door onderstaande (mogelijk meer actuele) registratie**

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

Register	ID
NTR-new	NL2698
NTR-old	NTR2835
Ander register	METC Medisch Spectrum Twente : P11-01
ISRCTN	ISRCTN wordt niet meer aangevraagd.

# Resultaten

Samenvatting resultaten N/A