In-home EEG monitoring in suspected epilepsy.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28676

Source
Nationaal Trial Register

Health condition

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

Sponsors and support

Primary sponsor: M.J.A.M. van Putten MD PhD
Medisch Spectrum Twente
Afdeling Klinische Neurofysiologie
Source(s) of monetary or material Support: High Tech Health Farm; subsidie verstrekt door provincie Overijssel

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. The number of hospital visits from first visit to diagnosis;

2. The time-to-diagnosis;

3. Direct and indirect costs related to the diagnostic procedure;

4. Usability of the EEG equipment including user experience;

5. Accuracy of computer algorithms for analysis of the EEG.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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

Contacts

Public

[default]

The Netherlands
Scientific

[default]
The Netherlands

Eligibility criteria

Inclusion criteria

1. Seeing neurologist for suspected epilepsy after first insult;

2. Age above 18 years;

3. No previous history of epilepsy .

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2011

Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion Date:	31-03-2011
Application type:	First submission

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
NTR-new	NL2698
NTR-old	NTR2835
Other	METC Medisch Spectrum Twente : P11-01
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A