Seizures in stroke patients.

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Firstly, measurement of the impact of seizures in stroke patients by comparing quality of life, cognitive function, disability, handicap, and mood between stroke patients with and without seizures.Secondly, recording information on treatment of post...

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

Summary

ID

NL-OMON32035

Source
ToetsingOnline

Brief title
Seizures in stroke patients.

Condition

- Seizures (incl subtypes)

Synonym
Poststroke epilepsy; fits in stroke patients

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Epilepsy, Quality of life, Seizures, Stroke

Outcome measures

Primary outcome

In the stroke group and the poststroke seizure group:

• cognitive function:

- the Mini-mental-state examination (MMSE)

- information processing task (Fepsy: CVST)

- either an auditive or visual reaction time task (Fepsy: auditive reaction task, Fepsy: visual reaction task)

• quality of life:

- EuroQol

- stroke-adapted Sickness Impact Profile (SA-SIP-30)

• disability: Barthel index

• handicap: modified Rankin score

• mood: depression and anxiety score (HADS)

• stroke severity: National Institutes of Health Stroke Scale (NIHSS)

• patient residence at present

• side effects: SIDAED list

In the poststroke seizure group:

• seizure count

• seizure severity: NHS3

• current AED treatment

• history of AED treatment including considerations made by the clinician to

switch AED treatment

In all participants:

• DNA testing for a polymorphism of the GRIN1 gene coding for the subunit NR1

of the NMDA receptor

Secondary outcome

No diversion between primary and secundary study parameters is made in this

observational study.

See for study parameters the previous section.

Study description

Background summary

The incidence of seizures increases with age. The etiology of most new-onset seizures in patients > 40 years old is cerebrovascular disease. Epidemiological studies have calculated the risk of post-stroke epilepsy for all stroke patients to be 2.5 to 4%1-4. Depending on the type of stroke, the severity and the location of the infarct or hemorrhage this percentage can increase to 62% 5. It is assumed that the occurrence of seizures diminishes quality of life, but it has not been studied in this specific population so far. Quality of life (QoL) in the general stroke population has been studied, but not related to the occurrence of seizures. Furthermore, it is possible that neurological outcome and cognition worsen after seizures6 7. Patients already damaged by stroke, encounter another neurologic problem which may cause anxiety and depression. Patients living at home may fear institutionalization.
Evaluating the problems encountered by stroke patients with seizures should be done by making a comparison between stroke patients with and without seizures.

When stroke patients experience a first late seizure, they tend to be treated with antiepileptic drugs. Finding the optimal antiepileptic treatment for these patients is difficult as there is little evidence based information on AED treatment in post-stroke epilepsy. This group of patients tends to be treated chronically with one of the traditional antiepileptic drugs (AEDs), like carbamazepine, phenytoin, phenobarbital, or valproate 8-10. These AEDs may however have serious side effects in chronic use. The effect of co-medication

may be influenced. In this population in which poly-drug treatment is common this is an important problem. Investigation of the impact of AED treatment on side effects, cognition and quality of life seems valuable for clinical practice. Some papers have reported which AEDs are used in this population,11 but more information on AED type, efficacy and tolerability is necessary.

All stroke patients are at risk for developing post-stroke epilepsy. When prophylactic medication would become available in the future, identification of stroke patients who are at the highest risk for developing post-stroke epilepsy is important. The NMDA receptor, one of the glutamate receptors, seems to play a role in the development of seizures. This receptor is formed by the NR1 subunit, together with one or more of the four different types of NR2 subunits (NR2A-NR2D). The NR1 subunit of the NMDA receptor is coded by the GRIN1 gene. Several polymorphisms of this gene are known. Rujescu et al (2005)12 determined a single nucleotide polymorphism (G2108A) for the GRIN1 gene in alcoholics with and without seizures and control patients. The A allele and A-containing genotypes were over-represented in patients with withdrawal-induced seizures compared to healthy volunteers and compared to alcoholics without a history of seizures. Perhaps the GRIN1 gene polymorphism can serve as a risk factor for the development of post-stroke seizures also.

Study objective

Firstly, measurement of the impact of seizures in stroke patients by comparing quality of life, cognitive function, disability, handicap, and mood between stroke patients with and without seizures.
Secondly, recording information on treatment of post stroke seizures, including AED treatment, information on seizure number and severity (efficacy), and side effects (tolerability).
Thirdly, assessment of GRIN1 polymorphism in stroke patients with and without seizures and in subjects without stroke of epilepsy to determine whether this polymorphism is a risk factor for the development of post-stroke seizures.

Study design

Observational, cross-sectional study, with only one single observation moment.
In this observational study, two groups of patients will be included:
group 1 stroke patients with epilepsy,
group 2 matched stroke patients without seizures or epilepsy.

A third group consisting of subjects without stroke of seizures participates in the DNA study.

Study burden and risks

When participating in the study, patients are asked to come to the outpatient

clinic to meet the study investigator. Patients are requested to perform a reaction time test and information processing task (taking approximately 15 minutes for both tests). They fill in two quality of life questionnaires (ca. 10 minutes), a questionnaire about anxiety and depression (ca. 5 minutes), and a questionnaire about side effects of the antiepileptic drug (ca. 15 minutes). The study investigator records a modified Rankin score, Barthel index (ca. 5 minutes), and mini-mental state examination (ca. 10 minutes), and performs a general history and neurological examination and records the NIHSS (ca. 10 minutes). To obtain DNA a mouth swab is taken.

In subjects without stroke or epilepsy a mouth swab is taken to obtain DNA. This takes less than 5 minutes and is painless.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion-criteria for the stroke patients with seizures/epilepsy:
• History of seizures or epilepsy after stroke, including all patients with one or more seizures at the beginning of a stroke or thereafter, in whom a diagnosis of post-stroke seizures or epilepsy was established based on clinical grounds.
• The last seizure is > 2 weeks ago at time of measurement (to avoid possible interference with cognitive function).
• The diagnosis of post-stroke epilepsy was made > 3 months ago.
• Age 18 to 90 years old.;Inclusion-criteria for the stroke patients without seizures or epilepsy:
• History of stroke
• No history of epileptic seizures or syncope of unknown origin.
• Matched with patients of the first group on the following criteria:
- age
- gender
- time since stroke
- stroke severity or modified Rankin score at stroke onset
- lacunar stroke vs. cortical stroke
- presence of cardiac emboli source;Inclusion-criteria for the participants without stroke or epilepsy:
- aged 18 years of older.
- no history of stroke, epileptic seizures, degenerative brain disease or brraintumor.

Exclusion criteria

Exclusion-criteria for all groups:
• Not able or willing to provide informed consent.
• Severe illness or cognitive decline preventing adequate investigations (including global aphasia)
• The patient objects against the use of medical records and/or body materials for scientific investigations (as recorded in Mirador)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2008
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	26-03-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	07-07-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	23-09-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL21994.068.08