Cognitive adverse effects of anti-epileptic drugs investigated using fMRI

Published: 19-04-2010
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Objective: To investigate active and resting state networks and other MR parameters in patients with epilepsy and to determine the possible influence of anti-epileptic drugs use.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Seizures (incl subtypes)
Study type	Observational invasive

Summary

ID

NL-OMON35526

Source
ToetsingOnline

Brief title
Cognitive adverse effects of AEDs investigated using fMRI

Condition

- Seizures (incl subtypes)

Synonym
convulsions, epilepsy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: anti-epileptic drugs, epilepsy, fMRI, side-effects

Outcome measures

Primary outcome

Main study parameters/endpoints: Network describing MR parameters, especially fMRI and functional connectivity; Relations between these parameters and changes in anti-epileptic drugs used.

Secondary outcome

The MR parameters and anti-epileptic drug use will be correlated with neuropsychological test results.

Study description

Background summary

Rationale: Anti-epileptic drugs have effects on brain functions. This sometimes leads to tolerability problems in the form of side effects. fMRI and other MR parameters can be used to study brain functions in detail, which may help us to understand (changes in) brain function when using anti-epileptic drugs. We hypothesize that such changes can be observed on the level of activation and functional connectivity between brain areas leading to changed networks.

Study objective

Objective: To investigate active and resting state networks and other MR parameters in patients with epilepsy and to determine the possible influence of anti-epileptic drugs use.

Study design

Study design: Observational and clinical comparative study, in patients with epilepsy.
The study is a proof of principal study. About fifty patients diagnosed with epilepsy using medication and developing objectively defined side effects will be investigated. The MR parameters will be correlated with the disappearing of the complaints and changes in neuropsychological test results after stopping the drug. When our hypotheses seem valid, we will see changes in the networks.

Study burden and risks

Besides the normal clinical evaluation the patient will undergo two MR scanning sessions (about 45 minutes in duration), two neuropsychological investigations (about 30 minutes in duration), two blood samples and filling out some questionnaires twice (about 10 minutes in duration). There is no extra benefit for the participating patients themselves. The extra risks for the patients participating in this study are less than minimal.

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

Age over 18 years old, able to give informed consent, using anti-epileptic drugs when

investigations take place.

Exclusion criteria

Absolute or relative contra-indications for MR scanning, unable to peform tasks in MR or unable to complete the questionnaires.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-04-2010
Application type:	First submission
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	NL22849.068.09