Cognitive adverse effects of anti-epileptic drugs investigated using fMRI

Published: 29-02-2012
Last updated: 30-04-2024

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	Recruitment stopped
Health condition type	Seizures (incl subtypes)
Study type	Observational invasive

Summary

ID

NL-OMON37523

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

Differences between the groups on network describing MR parameters, especially fMRI, functional connectivity and spectroscopy; Relations between these parameters with their anti-epileptic drug use.

Secondary outcome

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

Study description

Background summary

Anti-epileptic drugs have effects on brain functions. This sometimes leads to tolerability problems in the form of cognitive 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 (1) that such differences can be observed on the level of activation and functional connectivity between brain areas leading to changed networks and (2) that the appearance of cognitive side effects induced by AED treatment are related to changes in neurotransmitter concentration (GABA and/or Glu).

Study 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

Observational and clinical comparative study, in patients with epilepsy. The study is a proof of principal study. Seventy patients diagnosed with epilepsy using anti-epileptic drugs that have developed subjective complaints about their anti-epileptic drug treatment will be investigated. Half of them (thirty-five) are using topiramate or phenytoin and the other half of them

(thirty-five) are using lamotrigine or levetiracetam. The groups will be case-wise matched on important demographic factors: age, gender, educational level and on co-medication (carbamazepine or valproate). MRI examination and a neuropsychological investigation (including questionnaires) will be performed.

Study burden and risks

Besides the normal clinical evaluation the patient will undergo one neuropsychological investigation and filling out some questionnaires once (about 45 minutes in duration), one MR scanning session (about 60 minutes in duration) and one blood sample. 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

Public
Epilepsiecentrum Kempenhaeghe

Postbus 61
5590 AB Heeze
NL
Scientific
Epilepsiecentrum Kempenhaeghe

Postbus 61
5590 AB Heeze
NL

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 (phenytoin, topiramate, levetiracetam or lamotrigine) 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:	Recruitment stopped
Start date (anticipated):	05-04-2012
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	29-02-2012
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	NL38718.068.11