Pharmacogenetics and epilepsy; analyse van de respons op lamotrigine

Published: 30-10-2006
Last updated: 14-05-2024

To evelauate whether the presence of selected polymorphisms has an effect on the response to lamotrigine.

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

Summary

ID

NL-OMON29964

Source
ToetsingOnline

Brief title
Pharmacogenetics of lamotrigine as an antiepileptic drug

Condition

- Seizures (incl subtypes)

Synonym
epilepsy

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Epilepsie Instellingen Nederland (SEIN)
Source(s) of monetary or material Support: Op dit moment wordt het onderzoek betaald door geld uit de wetenschappelijke budgetten van de betrokken instellingen. Na verzameling van ongeveer de helft van het benodigde patientenaantal;zal een subsidie worden aangevraagd bij een collectebusfonds.

Intervention

Keyword: epilepsy, lamotrigine, pharmacogenetics

Outcome measures

Primary outcome

Presence of selected polymorphisms in the three patient groups.

Secondary outcome

Number of antiepileptic drugs used; epilepsy subtype; seizure type.

Study description

Background summary

Patients with the similar type of epilepsy and seizure type may respond differently to specific antiepilepltic drugs. The background for these differences is largely unknown. Possibly genetic differences, and especially polymorphisms, contribute to this variation in drug response. Polymorphisms are genetic variations that occur in more than 1% of the population.

Study objective

To evelauate whether the presence of selected polymorphisms has an effect on the response to lamotrigine.

Study design

After recruitment into the study, 20 ml of venous blood is collected from each patient and DNA is isolated from these blood samples. Recruited patients are divided into three groups: patients that became seizure free on lamotrigine; patients that did not achieve seizure freedom on lamotrigine, but did become seizure free on another antiepileptic drug or combination of drugs; treatment resistant patients.
Polymorphisms will be selected that may be of significance to the efficacy of lamotrigine. The presence of these polymorrphims will be assessed in the DNA of patients.

Study burden and risks

A 20 ml blood sample is collected once.

Contacts

Public
Stichting Epilepsie Instellingen Nederland (SEIN)

Postbus 563
8000 AN Zwolle
Nederland
Scientific
Stichting Epilepsie Instellingen Nederland (SEIN)

Postbus 563
8000 AN Zwolle
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

General inclusion criteria
1. Adult patients with cryptogenic or symptomatic localization-related epilepsy, manifesting in generalized tonic-clonic, complex partial and/or simple partial seizures.
2. Patients that are able to understand the written information about the study and are able to give informed consent.

Exclusion criteria

Exclusion criteria:
1. Patients failing valproate due to other reasons than persisting seizures despite a maximum tolerated dose (i.e. failure due to adverse effects on a starting dose of valproate, failure due to non-compliance etc).
2. Patients with generalized epilepsy and/or generalized absence-seizures and /or myoclonic seizures.
3. Acute or progressive neurological disease.
4. History of psychiatric disease or substance addiction.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL12085.058.06