Correlation between SV2A expression in tumour tissue and efficacy of levetiracetam in glioma patients with epilepsy.

Published: 05-03-2007
Last updated: 10-05-2024

Is SV2A expression in surgically removed tumour and tumour-surrounding tissue of glioma patients suffering from epilepsy correlated with their clinical response to levetiracetam?

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

Summary

ID

NL-OMON30525

Source
ToetsingOnline

Brief title
SV2A expression and levetiracetam response in glioma patients.

Condition

- Seizures (incl subtypes)

Synonym
epilepsy, seizures

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: UCB Pharma

Intervention

Keyword: epilepsy, glioma, levetiracetam, SV2A

Outcome measures

Primary outcome

The primary study parameter is the total number of seizures during the study period, which is 6 months for every indivicual patient.

Secondary outcome

The secondary study parameters will be time to drug withdrawal due to inadequate seizure control (if applicable). Other study parameters will be change in cognitive function, quality of life, and brain activity as measured by MEG at the end of the study, compared with baseline.

Study description

Background summary

Levetiracetam is a relatively novel anti-epileptic drug (AED), which has proven to be effective and well tolerated in many glioma patients with otherwise pharmacoresistant epilepsy. Moreover, levetiracetam has neither enzyme-inducing nor enzyme-inhibiting properties, which makes the drug particularly attractive for brain tumour patients, as they frequently receive chemotherapy and/or corticosteroids. Therefore, levetiracetam is the anti-epileptic drug of choice post-operatively in glioma patients suffering from epilepsy. Unfortunately, even with levetiracetam, a proportion of glioma patients is not free of seizures. It is unclear, however, which glioma patients benefit from levetiracetam treatment. Better selection of glioma patients with seizures for treatment with levetiracetam would avoid unnecessary and ineffective treatment with levetiracetam. Recently the synaptic vesicle protein 2A (SV2A) has been demonstrated to be the binding site for levetiracetam. It is suggested that the expression of SV2A is correlated with clinical response to levetiracetam. The determination of SV2A expression in brain (tumour) tissue might be used as a predictive tool for response to levetiracetam.

Study objective

Is SV2A expression in surgically removed tumour and tumour-surrounding tissue of glioma patients suffering from epilepsy correlated with their clinical response to levetiracetam?

Study design

Multi-centre observational cohort study.

Study burden and risks

The burden associated with participation consists of 1) a number of extra visits to the outpatients* department (at least at the time of inclusion, at 3 months, and at the end of the study (6 months)), 2) completing questionnaires regarding quality of life at the start and at the end of the study, 3) keeping a diary regarding the frequency and severity of epileptic seizures during 6 months, 4) a neuropsychological test battery at the start and at the end of the study, 5) examination through magnetoencephalography (MEG) at the start and at the end of the study (only for patients included at the VUmc), 6) blood sampling at the start and the end of the study. The risks associated with participation are minimal as levetiracetam is registered for monotherapy in patients with focal epileptic seizures, whether or not with secondary generalisation, which is the type of seizures glioma patients suffer from. If patients that are included into this observational study turn out to be refractory to treatment with levetiracetam during the study interval, patients will be converted to treatment with another AED, conform national and international guidelines on prophylaxis and treatment of epilepsy. This will be regarded as drug withdrawal due to inadequate seizure control. In our view, the burden and risks associated with participation are proportionate to the potential value of the research for the future treatment of glioma patients suffering from epilepsy. Ultimately, the results of this study could lead to better selection of glioma patients for treatment with levetiracetam, thereby avoiding unnecessary treatment in other glioma patients.

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

We will include adult (> 18 years) glioma patients who suffered from partial seizures, with or without secondary generalisation, preoperatively. Patients must have undergone surgery for their newly-diagnosed or recurrent glioma not more than 42 days previously and be treated with levetiracetam monotherapy at the time of inclusion.

Exclusion criteria

Patients who do not have a basic proficiency of the Dutch language, or are unable to communicate adequately (e.g. due to dysphasia) will be excluded.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2007
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL15305.029.06