

# A study comparing two anti-epileptic drugs in glioma patients with a first seizure

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON22812

### Source

Nationaal Trial Register

### Brief title

STING

### Health condition

Glioma patients with a first epileptic seizure

## Sponsors and support

**Primary sponsor:** Leiden University Medical Center

**Source(s) of monetary or material Support:** Team Westland

## Intervention

## Outcome measures

### Primary outcome

the percentage of patients with ongoing seizure freedom at 6 months

### Secondary outcome

- time to 6 month seizure freedom
- seizure outcome at 12 months
- level of toxicity and hospitalization rate due to treatment failure
- impact of seizures on HRQoL, cognitive complaints, anxiety/depression and performance status
- burden of epilepsy
- treatment response (e.g., maximum dosage of AED, use of add-on AED).
- progression-free and overall survival
- burden of epilepsy
- treatment response (e.g., maximum dosage of anti-epileptic drug, use of add-on anti-epileptic drug).
- progression-free and overall survival

## Study description

### Background summary

Currently, treatment with a specific anti-epileptic drug (AED) mainly depends on the physicians' preference, as there are no randomized controlled trials supporting the use of one specific anticonvulsant in glioma patients. The overall aim of this strategy study is to directly compare the effectiveness of treatment with levetiracetam or valproic acid in glioma patients with a first seizure. In addition, we aim to examine the level of toxicity, the impact of seizures on HRQoL, cognitive complaints, anxiety/depression, performance status and survival.

### Study objective

The aim of this study is to directly compare the effectiveness of treatment with levetiracetam or valproic acid in glioma patients with a first seizure

### Study design

Follow-up will be maximal 36 months. The timing of outcome assessment will be different for patients with a 3-monthly or 6-monthly follow-up schedule. The first 24 months, patients will be assessed at baseline and subsequently at every follow-up visit. Next, all patients

(regardless their follow-up schedule) will be assessed every 6 months.

## **Intervention**

Treatment with (A) levetriacetam, or (B) valproic acid

## **Contacts**

### **Public**

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## **Eligibility criteria**

### **Inclusion criteria**

- Histologically proven or suspected diffuse astrocytoma (Isocytate Dehydrogenase-1 (IDH-1) wildtype or IDH-1 mutated), diffuse oligodendroglioma (IDH-1 mutated and 1p/19q co-deleted), anaplastic astrocytoma (IDH-1 wildtype or IDH-1 mutated), anaplastic oligodendroglioma (IDH-1 mutated and 1p/19q co-deleted), glioblastoma (IDH-1 wild-type or IDH-1 mutated), or diffuse astrocytoma not otherwise specified (NOS), anaplastic astrocytoma NOS, oligodendroglioma NOS, oligoastrocytoma NOS, anaplastic oligoastrocytoma NOS, anaplastic oligodendroglioma NOS or glioblastoma NOS.
- Adult patients: ≥18 years of age
- First epileptic seizure, no longer than 2 weeks ago
- Monotherapy with antiepileptic drugs is considered most appropriate at the time of randomization

- Willing to provide written informed consent

## Exclusion criteria

- Previously treated with antiepileptic drugs, except emergency treatment in the past 2 weeks
- History of non-brain tumor related epilepsy
- Pregnancy
- History of a status epilepticus
- Presence of contra-indications for use of levetiracetam or valproic acid

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2017
Enrollment:	120
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	02-01-2017

Application type:

First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 50617

Bron: ToetsingOnline

Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
NTR-new	NL6547
NTR-old	NTR6735
CCMO	NL62477.058.17
OMON	NL-OMON50617

## Study results