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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22812

Source
NTR

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

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Eligibility criteria

Inclusion criteria

- Histologically proven or suspected diffuse astrocytoma (Isocytrate 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: ¡Ý18 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