Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Clinical trial on comparison of levetiracetam monotherapy and sodium valproate monotherapy on quality of life and seizure control in patients with brain tumor-related epilepsy

Protocol summary

Summary

Objectives: To compare quality of life and seizure control in patients with tumor-related epilepsy treated with levetiracetam and sodium-valproate Design: Randomized controlled trial Setting and conduct: We will enroll 23 patients by convenience sampling method, divided into two groups of levetiracetam and sodium-valproate randomly. Patients will be asked to fill the following questionnaires before and 6 months after starting their medication: Beck depression inventory (BDI-II), quality of life in epilepsy inventory (QOLIE-31-P), Beck anxiety inventory (BAI), mini-mental state examination (MMSE). They will be interviewed monthly, to evaluate seizure control and adverse effects. Blood tests will also be taken after 6 months. Major inclusion criteria: Patients with brain tumors and eplepsy, who had at least one seizure prior to having been referred to our center, and had never undergone prior antiepileptic drug (AED) therapy; or who had received previous AED without response; or with severe side effects with previous AED therapy. Major exclusion criteria: Patients with epilepsy prior to tumor onset; or with known severe liver disease. Intervention: Group 1: Levetiracetam starting dose is 250 mg BID and it is up titrated (500 mg/week) to 1.000– 3.000 mg/day, depending on seizure control and tolerability. Group 2: Sodium-valproate starting dose is 200 mg BID, and it is up titrated (200 mg/week) to 1000 – 3000 mg/day, depending on seizure control and tolerability. Main outcome measures: Quality of life, anxiety, depression, cognitive function, seizure control, neurological examination, and adverse effects are outcome variables that are measured and compared between two groups.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015052022340N1**
Registration date: **2015-12-26, 1394/10/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-26, 1394/10/05

Registrant information

Name

Somayyeh Sadat Teimouri

Name of organization / entity

Isfahan University of Medical Sicences

Country

Iran (Islamic Republic of)

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+98 31 3224 1034

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jafarmehvari@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research of Isfahan University of medical sciences Cobel Darou company

Expected recruitment start date

2015-05-31, 1394/03/10

Expected recruitment end date

2015-12-31, 1394/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Clinical trial on comparison of levetiracetam monotherapy and sodium valproate monotherapy on quality of life and seizure control in patients with brain tumor-related epilepsy

Public title
Quality of life and seizure control in patients with brain tumor-related epilepsy treated with levetiracetam monotherapy compared by sodium-valproate monotherapy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Patients with brain tumors and epilepsy characterized by simple or complex partial seizures, with or without secondary generalization; Patients who had at least one seizure prior to having been referred to our center, who had never undergone prior anti-epileptic drug (AED) therapy; Patients who had received previous AED (with a verification that the previous AEDs had been in the therapeutic range but not controlled; Patients with severe side effects with previous AED therapy. Exclusion criteria: Patients with epilepsy prior to tumor onset; Patient with known sever liver disease for Sodium-Valproate group.

Age
From **12 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **23**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study randomization will be performed through random number table, assigned to the samples to be divided into two groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Hezar Jarib St

City
Isfahan

Postal code
8174673461

Approval date
2014-10-29, 1393/08/07

Ethics committee reference number
393920

Health conditions studied

1

Description of health condition studied
brain tumor related epilepsy

ICD-10 code
G40

ICD-10 code description
Epilepsy

Primary outcomes

1

Description
seizure

Timepoint
nomber of seizure attack

Method of measurement
telephon call or visit of patient 0 and 6 month after add patients

2

Description
Quality of life

Timepoint
Start of the study and 6 months after the start point

Method of measurement
quality of life in epilepsy inventory (QOLIE-31-P)

3

Description
Anxiety

Timepoint
Start of the study and 6 months after the start point

Method of measurement
Beck anxiety inventory (BAI)

4

Description
Depression

Timepoint
Start of the study and 6 months after the start point

Method of measurement
Beck depression inventory (BDI-II)

5

Description
Cognitive function
Timepoint
Start of the study and 6 months after the start point
Method of measurement
mini-mental state examination (MMSE)

6

Description
Blood indices
Timepoint
Start of the study and 6 months after the start point
Method of measurement
Taking blood sample and send to laboratory

7

Description
Side effects
Timepoint
Monthly
Method of measurement
Interview (in-person and by telephone)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Levetiracetam starting dose is 250 mg BID and it is up titrated (500 mg/week) to 1.000–3.000 mg/day, depending on seizure control and tolerability.
Category
Treatment - Drugs

2

Description
Intervention group 2: Sodium-valproate starting dose is 200 mg BID, and it is up titrate (200 mg/week) to 1000 – 3000 mg/day, depending on seizure control and tolerability.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani comprehensive epilepsy center
Full name of responsible person
Dr.Jafar Mehvari
Street address
Kashani hospital, Kashani St
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Isfahan University of medical sciences
Full name of responsible person
Dr. Mahdi Nematbakhsh
Street address
Hezar Jarib St
City
Isfahan
Grant name
Grant code / Reference number
393920
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Isfahan University of medical sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
Cobel Darou company
Full name of responsible person
Dr. Somayyeh Sadat Teimouri
Street address
No 39, Alvand St, Arjantin Sq,
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Cobel Darou company
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Somayyeh Sadat Teimouri

Position

Neurology resident

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

Jafar Mehvari

Position

Associate professor of neurology

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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty