

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Study of efficacy and tolerability of adjunctive therapy with Zonisamide in adulthood intractable epilepsy

Protocol summary

Summary

The main objective of this study is to evaluate the tolerability and safety of Zonisamide as an adjunctive therapy in all kinds of Seizures that are resistant to routine treatment. The inclusion and exclusion criteria of this study are as following: Inclusion criteria: 1) Seizure frequency ≥ 4 per month in spite of treatment with 2 AED (Intractable Seizure) 2) Age above 17 3) Any type of Seizure Disorders Exclusion Criteria: 1) Having progressive encephalopathy or any structural disorders of central nervous system now or before taking part in this study 2) Having any diseases in other organ systems such as eyes, heart, blood, kidney, liver now or before taking part in this study 3) sulfunamide sensitivity 4) Married women in reproductive age 5) Using Acetazolamide as an AED 6) Not having any cooperation in using drug 7) Any severe side effects of drug 8) Not having consensus about continuation of the study Total number of patients are about 56. Zonisamide will be started in 50 mg twice a day then after 1 week clinical condition and side effect will be evaluated then 100 mg twice a day will be started up to 400 mg in 1st month based on clinical situation, then if necessary increasing dosage may be included. In these process number of seizures and side effects will be evaluated. All patients will be assessed by phone follow up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811153278N1**

Registration date: **2009-11-01, 1388/08/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-11-01, 1388/08/10

Registrant information

Name

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Name of organization / entity

Isfahan Medical University

Country

Iran (Islamic Republic of)

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+98 31 1261 5182

Email address

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Recruitment status

Recruitment complete

Funding source

Isfahan Medical College- Bakhtar Bioshimi Company in Kermanshah

Expected recruitment start date

2009-11-01, 1388/08/10

Expected recruitment end date

2010-06-01, 1389/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Study of efficacy and tolerability of adjunctive therapy with Zonisamide in adulthood intractable epilepsy

Public title

The Study of efficacy and tolerability of adjunctive therapy with Zonisamide in adulthood intractable epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Seizure Frequency ≥ 4 per month in spite of treatment with 2 AED (Intractable Seizure) 2) Age above 17 3) Any types of Seizure Disorders
Exclusion Criteria: 1) Having progressive encephalopathy or any structural disorders of central nervous system now or before taking part into this study 2) Having any diseases such as eyes, heart, blood, kidney, liver now or before taking part into this study 3) sulfonamide sensitivity 4) Married women in pregnancy ages 5) Using Acetazolamide as an AED 6) Not having any cooperation in using drug 7) Any severe side effects of drug 8) Not having consensus about continuation of the study

Age

From **17 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences and Health Services

Street address

Hezar Jarib St-Isfahan

City

Isfahan

Postal code

Approval date

empty

Ethics committee reference number

289047

Health conditions studied

1

Description of health condition studied

Epilepsy

ICD-10 code

G40

ICD-10 code description

Episodic and paroxysmal disorders

Primary outcomes

1

Description

Seizure frequency

Timepoint

1 week, 2 week, 3 week, 1 month, 2 month, 3 month

Method of measurement

assessment of seizure frequency with asking from patients and filling questionnaire

2

Description

Side effects

Timepoint

1st week, 2nd week, 3rd week, 4th week, 2nd month, 3rd month

Method of measurement

Assessment of side effect by asking patients and filling a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Treatment with Zonisamide, Capsule 50, 100mg, oral, for 3 months. follow up every week for increasing doses based on clinics and side effects-Max dose is 600 mg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Azahra Hospital in Isfahan

Full name of responsible person

Street address

Alzahra Hospital, Sefeh st.,

City

Isfahan

2

Recruitment center

Name of recruitment center

Kashani Hospital in Isfahan

Full name of responsible person

Street address

Kashani st.,

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University Of Medical Sciences and Health Services

Full name of responsible person

Dr Mohammad Reza Najafi

Street address

Azahra Hospital, Soffeh st.,

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan University Of Medical Sciences and Health Services

Proportion provided by this source

100

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 Medical University

Full name of responsible person

Dr Mohammad Reza Najafi

Position

Associate Professor

Other areas of specialty/work

Street address

Number3, Behnaz close, Bagh beh Alley, Tohid st.,

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najafi@med.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan Medical University

Full name of responsible person

Dr Mohammad Reza Najafi

Position

Associate Professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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