

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

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

#### Protocol summary

2009-11-01, 1388/08/10

#### 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  $\geq 4$  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

#### Registrant information

##### Name

Sepehr Haghghi

##### Name of organization / entity

Isfahan Medical University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1261 5182

##### Email address

s\_haghghi@edc.mui.ac.ir

#### 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) Sizure Frequency  $\geq 4$ per month inspite 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 structral disorders of central nervous system now or before takeing part into this study 2) Having any diseases such as eyes, heart, blood, kidney, liver now or before taking part into this study 3) sulfunamide 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 abot 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**

assesment 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**

Assesment 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.,

**City**

Isfahan

**Postal code**

**Phone**

+98 31 1261 5182

**Fax**

**Email**

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**

**Street address**

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

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**Email**

najafi@med.mui.ac.ir

**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*