

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Effect of Levetiracetam mono therapy in comparison with Sodium Valproate on juvenile myoclonic epilepsy

#### Protocol summary

##### Summary

This study is a single blind clinical trial that will be performed in Isfahan city. The study population consists of all patients who Juvenile Myoclonic Epilepsy (JME) has been diagnosed in them for the first time and referred to the epilepsy clinic of Kashani hospital in Isfahan. The sample size is 20 samples collected using simple random sampling. Before start of Levotiracetam (LEV), informed consent from all patients will be taken. The 20 patients will randomly divide into two groups of 10, the LEV group and the Valproate sodium group. The course of treatment will be 6 to 12 months after initial the treatment. The first follow-up of patients will be after two weeks and then will be on a monthly basis. In every visit the doctor asks the number and type of seizures and the side effects of the drugs. Also examinations and assessments, EEG, vital signs and weight will be recorded. The inclusion criteria includes patients with JME and the exclusion criteria includes every diseases that its treatment in-tract with Valproate sodium and LEV. To ensure patient safety, before entering the study and every three months, liver enzymes, blood urea, creatinine and CBC of the patients will be measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014083018973N1**

Registration date: **2015-09-26, 1394/07/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-09-26, 1394/07/04

##### Registrant information

##### Name

Morteza Yousefi

##### Name of organization / entity

Shahrekord University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3777 2833

##### Email address

yosefi.m@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahrekord University of Medical Sciences

##### Expected recruitment start date

2014-06-21, 1393/03/31

##### Expected recruitment end date

2014-12-21, 1393/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Levetiracetam mono therapy in comparison with Sodium Valproate on juvenile myoclonic epilepsy

##### Public title

Compare valproate Sodium and Levetiracetam effects on epilepsy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria included patients how have JME (Juvenile Myoclonic epilepsy ) with two myoclonus and no EEG changes; or a Myoclonus with EEG changes, which this changes include specific changes (3-6Hz spike / polyspike slow wave discharge); epilepsy should start at

8 to 25 years old. The exclusion criteria included, neurological disorders; mental disorder; history of pseudoseizures; history of mental or mood disorder; the use of drugs affecting the central nervous system in a month before beginning of the study; metabolic disorders; infectious disease; malignancy; pregnancy and disease that their treatment interact with valproate sodium or Leveteracetam.

#### **Age**

From **8 years** old to **25 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **20**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Shahrekord University of Medical Science

##### **Street address**

Headquarter of Shahrekord University of Medical Science, Kashani Avn, Shah re-kord, Iran

##### **City**

Shahrekord

##### **Postal code**

8174798866

#### **Approval date**

2014-05-23, 1393/03/02

#### **Ethics committee reference number**

93-3-2

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Epilepsy

#### **ICD-10 code**

G40.3

#### **ICD-10 code description**

Generalized idiopathic epilepsy and epileptic syndromes

## **Primary outcomes**

### 1

#### **Description**

Electro encephalo gram (EEG) changes

#### **Timepoint**

Before, 3 months and 6 months after initial treatment

#### **Method of measurement**

Electro encephalo gram (EEG) that is taken by EEG machine. This changes contains 3-6 Hz Bilateral spike/polyspike slow wave discharge

### 2

#### **Description**

Count of seizures after treatment

#### **Timepoint**

After ending the period of treating (6 months after initial treatment)

#### **Method of measurement**

According to patients and their fellows history

### 3

#### **Description**

Count of myoclonus after treatment

#### **Timepoint**

3 and 6 months after initial treatment

#### **Method of measurement**

According to patients and their fellows history

## **Secondary outcomes**

### 1

#### **Description**

Sodium valproate side effects, that contains Asthenia, Headache, Smnolence, Cough, Nervousness, Amnesia, Ataxia, Depression, Nuasea, Vomiting, Tremor, Alopesia, Diziness, Dyspepsia, Rash, Weight Gain, Increase or decrease of appetite

#### **Timepoint**

3 and 6 months after initial treatment

#### **Method of measurement**

According to asking from patient and chek list

### 2

#### **Description**

Leveteracetam side effects that contains Asthenia, Headache, Smnolence, Cough, Nervousness, Amnesia, Ataxia, Depression, Nuasea, Vomiting, Tremor, Alopesia, Diziness, Dyspepsia, Rash, Weight Gain, Increase or decrease of appetite

#### **Timepoint**

3 and 6 months after initial treatment

#### **Method of measurement**

According to asking from patient and chek list

## Intervention groups

### 1

#### Description

case group will be treated with 250 mg LEV tablet and the drug dose will be increased until the patient will be seizure free. The maximum dose of LEV is 2500mg daily.

#### Category

Treatment - Drugs

### 2

#### Description

The control group will be treated with 10-15 mg/kg sodium valporate and the drug dose will be increased until the patient will be seizure free. The maximum dose of sodium valporate is 30-60 mg/kg.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Epilepsy clinic of Kashani hospital of Isfahan

##### Full name of responsible person

Dr Jafar Mehvari

##### Street address

Epilepsy clinic, Kashani hospital, Kashani Avn, Isfahan, Iran

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Deputy for research affairs of Shahrekord University of Medical Science

##### Full name of responsible person

Dr Mahmood Mobasheri

##### Street address

Deputy for research affairs, Headquarter of Shahrekord University of Medical Science, Kashani Avn, Shah re-kord, Iran

##### City

Shahrekord

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Deputy for research affairs of Shahrekord University of Medical Science

#### 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 University of Medical Science

##### Full name of responsible person

Dr Jafar Mehvari

##### Position

Associate Professor of Neurology

##### Other areas of specialty/work

##### Street address

Epilepsy clinic, Kashani Hospital of Isfahan, Kashani Avn, Isfahan, Iran

##### City

Isfahan

##### Postal code

##### Phone

+98 31 3777 2833

##### Fax

##### Email

Jafarmehvari@med.mui.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Isfahan University of Medical Science

##### Full name of responsible person

Dr Jafar Mehvari

##### Position

Associate Professor of Neurology

##### Other areas of specialty/work

##### Street address

Epilepsy clinic, Kashani hospital of Isfahan, Kashani Avn, Isfahan, Iran

##### City

Isfahan

##### Postal code

##### Phone

+98 31 3777 2833

##### Fax

##### Email

Jafarmehvari@med.mui.ac.ir

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Shahrekord University of Medical Science

**Full name of responsible person**

Morteza Yousefi

**Position**

Medical student

**Other areas of specialty/work****Street address**

Student komitte research, deputy .. affairs,  
Shahrekord University of Meccical Science, Kashani  
Avn, Shah re-kord, Iran

**City**

Shahrekord

**Postal code****Phone**

+98 38 3334 2414

**Fax**

+98 38 3334 2414

**Email**

M,yousefi.d68@gmail.com

**Web page address****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*