Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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 Scince, 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 mounths and 6 mounths after inital 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 mounths after initial treatment)

Method of measurement
According to patients and thier fellows history

3

Description
Count of myoclonus after treatment

Timepoint
3 and 6 mounths after initial treatment

Method of measurement
According to patients and thier fellows history

Secondary outcomes

1

Description
Sodium valporate 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 mounths 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 mounths 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 Scince
Full name of responsible person
Dr Mahmood Mobasheri
Street address
Deputy for research affairs, Headquarter of Shahrekord University of Medical Scince, 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 Scince
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 Scince
Full name of responsible person
Dr Jafar Mehvari
Position
Associate Professor of Neurology
Other areas of specialty/work
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Person responsible for updating data

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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