

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Investigation of pyridoxine effect on behavioral adverse events of levetiracetam in adult patients with idiopathic generalized tonic-clonic epilepsy; A randomized double-blind placebo-controlled clinical trial

#### Protocol summary

##### Study aim

Investigation of pyridoxine effect on behavioral side effects of levetiracetam in adult patients with idiopathic generalized epilepsy

##### Design

This is a two-arm parallel group randomized double-blind placebo-controlled trial with sample size of 50 patients

##### Settings and conduct

Patients will be discussed about the study and will sign informed consent. complete demographic data and history will be registered. After filling SCL-90-R questionnaire and randomization, patients will be divided into two groups and will be treated by pyridoxine 40mg/d or placebo 1 tab/d for 21 days. After 3 weeks they will be visited by the same neurologist again and efficacy of intervention will be reassessed by SCL-90-R questionnaire. The patients will be asked about subjective improvement, seizure frequency and drug withdrawal (time and cause) and data will be registered.

##### Participants/Inclusion and exclusion criteria

Adult patients with idiopathic generalized epilepsy who have been treated with levetiracetam in recent month and reported behavioral side effects will be included. Those who are pregnant, mentally retarded, have a history of psychiatric disease, alcohol or drug abuse, or complain of psychosis will be excluded.

##### Intervention groups

Group A: pyridoxine tablet 40mg once daily Group B: placebo tablet once daily.

##### Main outcome variables

Behavioral side effects; Withdrawal rate of levetiracetam due to behavioral side effects; Time to withdrawal of levetiracetam due to behavioral side effects

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180406039205N1**  
Registration date: **2019-12-28, 1398/10/07**  
Registration timing: **prospective**

Last update: **2019-12-28, 1398/10/07**

Update count: **0**

##### Registration date

2019-12-28, 1398/10/07

##### Registrant information

##### Name

Nasim Tabrizi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3334 3015

##### Email address

nasimtabrizi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-01, 1398/10/11

##### Expected recruitment end date

2020-07-01, 1399/04/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigation of pyridoxine effect on behavioral adverse

events of levetiracetam in adult patients with idiopathic generalized tonic-clonic epilepsy; A randomized double-blind placebo-controlled clinical trial

**Public title**

Effect of pyridoxine on behavioral side effects of levetiracetam

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age  $\geq 18$  years Patients affected by idiopathic generalized epilepsy Patients who are treated by levetiracetam (Levebel, Cobel darou) in recent month Complaint of behavioral problem Patient's consent for participation

**Exclusion criteria:**

History of known psychiatric disease Pregnancy Incidence of psychotic side effects including hallucination, psychosis, suicidal idea or attempt Treatment with psychiatric medications Alcohol or drug abuse Mental retardation to the degree that intervenes comprehension and response to questionnaire

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The patients will be randomized by simple randomization method with 1:1 rate using online software ([www.graphpad.com/quickcalcs/randMenu](http://www.graphpad.com/quickcalcs/randMenu))

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Both drugs and placebo with similar shape and color will be put in similar coded pockets (21 pills in each pocket) and will be given to patients. None of the patient, investigator and outcome assessor will know about type of intervention.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences.

**Street address**

Mazandaran University of Medical Sciences, Valiasr Highway, Sari, Iran

**City**

Sari

**Province**

Mazandaran

**Postal code**

48157-33971

**Approval date**

2019-11-13, 1398/08/22

**Ethics committee reference number**

IR.MAZUMS.REC.1398.1141

**Health conditions studied****1****Description of health condition studied**

Epilepsy

**ICD-10 code**

G40

**ICD-10 code description**

Epilepsy and recurrent seizures

**Primary outcomes****1****Description**

Efficacy of pyridoxine in treatment of behavioral side effects

**Timepoint**

before intervention and 3 weeks after intervention

**Method of measurement**

Symptom checklist-90-revised (SCL-90-R) questionnaire

**2****Description**

Withdrawal rate of levetiracetam due to behavioral side effects

**Timepoint**

3 weeks

**Method of measurement**

Patient interview

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention Pyridoxine, 40mg tablet (Darou pakhsh, Iran) once daily

### Category

Treatment - Drugs

## 2

### Description

Control group: Placebo tablet with the same shape and color as pyridoxine, once daily

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Bu Ali Sina Hospital

#### Full name of responsible person

Nasim Tabrizi

#### Street address

Neurology department, Bu Ali Sina hospital, Pasdaran Blvd., Sari.

#### City

Sari

#### Province

Mazandaran

#### Postal code

4815838477

#### Phone

+98 11 3334 3015

#### Fax

#### Email

nasimtabrizi@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Mazandaran University of Medical Sciences

#### Full name of responsible person

Majid Saeedi

#### Street address

Mazandaran University of medical sciences, Valiasr highway, Imam Sq., Sari

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#### Phone

+98 11 3304 4000

#### Email

n.tabrizi@mazums.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Sari University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Mazandaran University of Medical Sciences

#### Full name of responsible person

Nasim Tabrizi

#### Position

Assistant professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Neurology

#### Street address

Neurology department, Bu Ali Sina hospital, Pasdaran Blvd., Sari

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mazandaran University of Medical Sciences

#### Full name of responsible person

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Assistant professor

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Subspecialist

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Nasim Tabrizi  
**Position**  
Assistant professor  
**Latest degree**  
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**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

The reason for not sharing IPD is that in consent form we stipulate that patient's questionnaires will only be reviewed by investigators of this study and we will only publish the overall results in form of paper, etc.

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

We will share study protocol and informed consent with other researchers.

### When the data will become available and for how long

The shared data will be available based on the instructions of journal in which the paper will be published.

### To whom data/document is available

Researchers who work in academic institutions

### Under which criteria data/document could be used

-

### From where data/document is obtainable

The applicants can contact the researchers by following email : n.tabrizi@mazums.ac.ir

### What processes are involved for a request to access data/document

After receiving the applicant's email in mentioned time interval, related data will be sent back to him/her in 2 weeks.

### Comments