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 >=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)
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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saeedi
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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
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Person responsible for updating data

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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