Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluating the Effect of Levetiracetam on Benzodiazepine Withdrawal Syndrome in Comparison with Placebo

Protocol summary

Study aim

-Evaluating the effect of Levetiracetam on the duration of hospital stay and appropriate management of patients with symptoms of Benzodiazepine withdrawal syndrome -Assessing the severity of symptoms in Benzodiazepine withdrawal syndrome -Evaluating the dose of Clonazepam needed in patients experiencing Benzodiazepine withdrawal syndrome, after taking Levetiracetam and after taking placebo, and comparing the two of them -Mitigating the adverse effects and troubles caused by Benzodiazepine withdrawal

Design

This is a single-blind, parallel clinical trial, with two groups consisting of a drug or main group and a placebo or control group. Two-Digit randomizing table was used.

Settings and conduct

This clinical trial takes place in Roozbeh hospital, and is supervised by a clinical pharmacist, a neurologist and a pharmacy student.The drugs are given to patients in the ward by the nurses and the patients are not aware of their groups. CIWA-B questionnaire is filled by one of the supervisors.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who have been taking Benzodiazepines for at least 3 months and have not ceased using them for more than a month Exclusion Criteria: Patients diagnosed with acute and major psychological disorders, schizophrenia, epilepsy, or concurrent neurological disorders, e.g. Multiple Sclerosis Patients with a history of taking Levetiracetam or receiving concurrent Gabapentin or Carbamazepine in the last six months Patients younger than 15 years of age Allergic reactions to Levetiracetam or its excipients Severe adverse drug reactions

Intervention groups

Prescribing 500 milligrams of Levetiracetam in the drug group, for 2 weeks, 2 times a day Prescribing placebo in the control group, for 2 weeks, 2 times a day

Main outcome variables

Duration of hospitalization-CIWA-B sum of scores-Dose of the Clonazepam needed

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200701047979N1**
Registration date: **2020-07-20, 1399/04/30**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-20, 1399/04/30**
Update count: **0**

Registration date

2020-07-20, 1399/04/30

Registrant information

Name

Sheida Javid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 7260

Email address

sh.javid@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-28, 1399/04/08

Expected recruitment end date

2021-06-29, 1400/04/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the Effect of Levetiracetam on Benzodiazepine Withdrawal Syndrome in Comparison with Placebo

Public title
Effect of Levetiracetam on Benzodiazepine Withdrawal Syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who had been taking Benzodiazepines for at least three months, and have not discontinued them for more than one month.

Exclusion criteria:
Patients diagnosed with acute and major psychological disorders, schizophrenia, epilepsy, or concurrent neurological disorders, e.g. Multiple Sclerosis Patients with a history of taking Levetiracetam or receiving concurrent Gabapentin or Carbamazepine in the last six months Patients younger than 15 years of age Allergic reactions to Levetiracetam or its excipients Severe adverse drug reactions

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **39**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling takes place when a patient is referred to the emergency room of Roozbeh hospital, and he/she meets the study’s inclusion and exclusion criteria. For sampling allocation, permuted block randomization technic was used to prepare a randomizing table.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients participating in the study

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
VCR, 6th Floor, Tehran University of Medical Sciences Central Building, Ghods Street, Keshavarz Boulevard, Tehran

City
Tehran

Province
Tehran

Postal code
1417653911

Approval date
2020-03-07, 1398/12/17

Ethics committee reference number
IR.TUMS.TIPS.REC.1398.212

Health conditions studied

1

Description of health condition studied
Benzodiazepine Withdrawal Syndrome

ICD-10 code
T42.4X5

ICD-10 code description
Adverse effect of benzodiazepines

Primary outcomes

1

Description
Sum of Scores for CIWA-B Questionnaire

Timepoint
At benzodiazepine cessation and before taking Levetiracetam, then 2 weeks after taking Levetiracetam

Method of measurement
CIWA-B Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: patients in this group are given placebo 2 times a day for 2 weeks-The placebos are the exact physical replica of Levetiracetam tablets manufactured by Abidi Pharmaceutics. All the excipients are chemically the same and only the API (Active Pharmaceutical Ingredient) is removed.

Category

Placebo

2

Description
Intervention group: patients in this group are given 500 milligrams of Levetiracetam 2 times a day for 2 weeks.- Both Levetiracetam tablets and the placebos are manufactured by Abidi Pharmaceutics.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh Psychiatric Hospital
Full name of responsible person
Sheida Javid
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Sponsors / Funding sources

1

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Email
research@tums.ac.ir
Web page address
http://research.tums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
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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
There is no further information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Changes in CIWA-B total scores
When the data will become available and for how long
starting 3 months after publication
To whom data/document is available
Available to industrial or clinical pharmacists, and also to neurologists
Under which criteria data/document could be used
Please contact us beforehand.
From where data/document is obtainable
Sheida Javid via sh-Javid@student.tums.ac.ir or sh.javid@yahoo.com
What processes are involved for a request to access data/document
Please contact us beforehand.
Comments