Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of efficacy of Melatonin add on routine anti-epileptic drug regimen versus placebo in adult epileptic patients

Protocol summary

Study aim

Evaluation of the effectiveness of melatonin add on to the routine anti-epileptic treatment of epileptic patients compared with placebo

Design

This study is a randomized, double-blind, placebo-controlled clinical trial that recruited patients from Vali-Asr Hospital (Zanjan, Iran). The study was conducted in accordance with the Declaration of Helsinki and International Council for Harmonization Good Clinical Practice guidelines and approved by the independent ethics committee at Zanjan University of Medical Sciences before patient enrollment was commenced.

Settings and conduct

This study is a randomized, double-blind, placebo-controlled clinical trial that recruited patients from Vali-Asr Hospital (Zanjan, Iran). All patients and individuals involved in data collection will be blinded.

Participants/Inclusion and exclusion criteria

inclusion criteria: Adult patients (18 ≤ Ages ≤ 60 years old) with diagnosed idiopathic generalized tonic-clonic seizure and a history of 1-4 episodes of seizure within 4 months ago, which had a therapeutic level of anti-epileptic drugs(Valproate). Exclusion criteria: 1. history of any recent traumatic brain injury 2. cerebral ischemia/TIA/stroke 3. patients with neuroendocrinal tumors 4. history of any invasive neurosurgical/non-invasive neuropsychiatric procedure 5. Pregnant women 6. patients with a history of allergy to valproate or melatonin 7. patients with drug/alcohol abuse 8. patients with any hepatic dysfunction.

Intervention groups

patients prescribed 3mg melatonin tablet (add-on valproate) single dose daily, 1hour before bedtime and continued for 8 weeks

Main outcome variables

The severity of attacks; Frequency of attacks; sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101209005352N4**
Registration date: **2021-02-18, 1399/11/30**
Registration timing: **retrospective**

Last update: **2021-02-18, 1399/11/30**
Update count: **0**

Registration date

2021-02-18, 1399/11/30

Registrant information

Name

Mehdi Maghbooli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-17, 1396/07/25

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

2017-10-24, 1396/08/02

Actual recruitment end date

2019-11-21, 1398/08/30

Trial completion date

2020-02-09, 1398/11/20

Scientific title

Evaluation of efficacy of Melatonin add on routine anti-epileptic drug regimen versus placebo in adult epileptic patients

Public title
Melatonin add on anti epileptic drug
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range 18_45 years 1_4 general idiopathic tonic-clonic seizure attacks in the last 4 months Patients with a therapeutic level anti epileptic drugs
Exclusion criteria:
Patient dissatisfaction Patients are intubation Loss of consciousness Patients without a therapeutic level anti epileptic drugs
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to the melatonin and placebo groups with a 1:1 ratio. The blocking method will be used to randomize the allocation of samples. To do this, a computer coding system is used. Each patient will be assigned a random 6-digit code, which will be associated with the same code on a bottle of drug. Only the nurse who fills the bottles will know the contents and the relevant code. This nurse will have no other role in the study. The placebo and melatonin pill will look the same.
Blinding (investigator's opinion)
Double blinded
Blinding description
All patients and physicians and all personnel involved in the data collection process will be unaware of the medicinal nature of the containers.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences
Street address
Gavazang
City
Zanjan
Province
Zanjan
Postal code
49123-56212
Approval date
2017-10-17, 1396/07/25
Ethics committee reference number
IR.ZUMS.REC.1396.180

Health conditions studied

1

Description of health condition studied
seizure
ICD-10 code
G40
ICD-10 code description
Epilepsy and recurrent seizures

Primary outcomes

1

Description
Frequency and severity of seizures
Timepoint
After 8 and 18 weeks of treatment
Method of measurement
According to Chalfont questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Melatonin (patients prescribed 3mg melatonin tablet (add-on valproate) single dose daily, 1 hour before bedtime and continued for 8 weeks.)
Category
Treatment - Drugs

2

Description
Control group: Placebo (patients prescribed placebo

tablet (add-on valproate) single dose daily, 1 hour before bedtime and continued for 8 weeks.)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital (Zanjan. Iran)

Full name of responsible person

Dr Mehdi Maghbooli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology, Zanjan University of Medical Sciences

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۴۹۱۲۶-۴۹۵۱۵

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Mehdi Maghbooli

Position

Associate professor

Latest degree

Specialist

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)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available