Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

The Effect of Melatonin in patients with intractable epilepsy

Protocol summary

Summary

The aim of the present study is to determine the effect of Melatonin on sleep quality and seizure attacks in patients with intractable epilepsy A semi clinical trial will be carried out on 30 patients with intractable seizure. Samples will be selected from neurology clinics of Arak city. After physical and neurological examination the demographic and Pittsburgh questionnaire will be fulfilled and all patients will receive melatonin 3 mg at bedtime for 2 months. Finally patients will be reexamined and for second time complete the demographic and Pittsburgh questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015013117811N7**
Registration date: **2015-02-11, 1393/11/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-11, 1393/11/22

Registrant information

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Shayan Amjadi
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Recruitment status

Recruitment complete

Funding source

This study will be supported by a grant from Office of Vice Chancellor for Research of Arak university of Medical Sciences

Expected recruitment start date

2013-06-01, 1392/03/11

Expected recruitment end date

2014-03-01, 1392/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Melatonin in patients with intractable epilepsy

Public title

Melatonin and Epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria : age 15–80 years ; clinically definitive intractable epilepsy confirmed by a neurologist ; presented to the Neurology clinics at Arak city between June, 2013 and March 2014 ; normal clinical exam ;Treatment with at least three appropriate anti-epileptic drugs had failed to control seizures in all patients exclusion criteria : neurodegenerative disorders ; brain neoplasm ; chronic hematological , cardiac , hepatic, renal or thyroid disorder ; history of smoking and addiction to drugs or alcohol.

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of medical science
Street address
Arak University of Medical Sciences ,Sardasht , Arak , Iran
City
Arak
Postal code
Approval date
2013-05-22, 1392/03/01
Ethics committee reference number
92-157-12

Health conditions studied

1

Description of health condition studied
intractable epilepsy
ICD-10 code
G40
ICD-10 code description
Epilepsy

Primary outcomes

1

Description
the number of monthly seizure episodes
Timepoint
baseline and after 2 months
Method of measurement
patients self report

2

Description
Sleep quality
Timepoint
baseline and after 2 months
Method of measurement
PSQI questionaries

Secondary outcomes

empty

Intervention groups

1

Description
melatonin 3 mg nightly for 2 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology clinics of Arak city
Full name of responsible person
dr. Fardin Faraji
Street address
Arak University of Medical Sciences , Sardasht , Arak , Iran
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Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences , Office of Vice Chancellor for Research
Full name of responsible person
Dr.Mohammad Rafii
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Arak University of Medical Sciences , Sardasht , Arak , Iran
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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
Arak University of Medical Sciences , Office of Vice Chancellor for Research
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

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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