Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 2026

Investigation Effect of melatonin, vitamin E administration on EEG and sleep quality in shift worker Nurses

Protocol summary

Summary

The research aimed to investigate the effect of melatonin and vitamin E on working shift nurses' sleep in ValiAsr Hospital located in Arak. Hence, the study employed a randomized, single-blind, clinical trial study. Moreover, the investigative group was blind to the type of therapy. The research plan was to select 90 nurses aged 20 to 45. The inclusion criteria were to have at least one year of work experience, six night shifts per month, no second job, andno history of sleep problems. Theparticipants' exclusion criteria included drug intolerance, no use of drugs within two months of and diagnosis of systemic diseases. Participants were divided into one control group and three groups that underwent three types of intervention (melatonin group, vitamin E group, and melatonin/ vitamin E group). Melatonin was used at a dose of mg / day3 and vitamin E at a dose of UI / day 200 for two months. Furthermore, participants completed Pittsburgh sleep qualityquestionnaire both in the beginning and two months after the initiation of treatment. Finally, findings were compared for each groups both prior to and subsequent to the intervention. The main outcome variables included sleep quality and EEG features.

General information

Acronym
EEG

IRCT registration information
IRCT registration number: **IRCT2015040621626N1**
Registration date: **2017-04-21, 1396/02/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2017-04-21, 1396/02/01

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source
Research and Technology Vice Chancellor, ArakUniversity of Medical Sciences

Expected recruitment start date
2015-04-21, 1394/02/01

Expected recruitment end date
2015-08-23, 1394/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation Effect of melatonin, vitamin E administration on EEG and sleep quality in shift worker Nurses

Public title
Effect of melatonin and vitamin E on working shift nurses' sleep in ValiAsr Hospital located in Arak

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: to have at least one year of work experience؛ six night shifts per month؛ no second job؛ no

history of sleep problems؛ no special underlying disease such as gland diseases and thyroid؛ no use of certain medications such as such as benzodiazepines and anticonvulsants, maximum age of 40 years. Exclusion criteria: Intolerance of melatonin or vitamin E؛recent history of melatonin or vitamin E for any other reason؛ a history of intolerance of melatonin or Vitamin E’s oral use؛ diagnosis of chronic systemic diseases (other than diabetes and hypertension)؛ and autoimmune disorders؛ infections؛ lack of regular drug use within two months of prescribed drugs؛ lack of consent to participate in the study؛ the nurses participated in the study who can’t be reachable for the intervention or follow-up were excluded.

Age
From **22 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Arak University of Medical Sciences Ethics committee

Street address
Arak University of Medical Sciences, Almolhoda st.

City
Arak

Postal code
3819693345

Approval date
2015-02-23, 1393/12/04

Ethics committee reference number
93-175-14

Health conditions studied

1

Description of health condition studied
Sleep disorders

ICD-10 code
G47

ICD-10 code description
Sleep disorders

Primary outcomes

1

Description
Sleep quality

Timepoint
Befor intervention and 2 month after start of intervention

Method of measurement
TPR and weight.PSQI

2

Description
EEG waves

Timepoint
Befor intervention and 2 month after start of intervention

Method of measurement
Electroencephalogram

Secondary outcomes

empty

Intervention groups

1

Description
Intervention of the first group: receiving a tablet of melatonin 3 mg orally every night for two months, except for working night shifts

Category
Treatment - Drugs

2

Description
Intervention of the second group: receiving a tablet of vitamin E/ 200 Units, orally every day for two months

Category
Treatment - Drugs

3

Description
Intervention of the third group: receiving a tablet of melatonin 3 mg orally every night for two months, except for working night shifts and a tablet of vitamin E/ 200 Units, orally every day for two months

Category
Treatment - Drugs

4

Description
Control group: No intervention and measuring outcome variables
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Dr. Mohsen Ebrahimi Monfared
Street address
Valiasr Hospital, Arak
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research and Technology Vice Chancellor, Arak University of Medical Sciences
Full name of responsible person
Mohsen Ebrahimi Monfared
Street address
Arak.Islamic Republic of 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
Research and Technology Vice Chancellor, Arak University of Medical Sciences
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