

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 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, and no history of sleep problems. The participants' 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 / day 3 and vitamin E at a dose of UI / day 200 for two months. Furthermore, participants completed Pittsburgh sleep quality questionnaire both in the beginning and two months after the initiation of treatment. Finally, findings were compared for each group 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

Name

Zahra Gohari

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research and Technology Vice Chancellor,
Arak University 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

Before intervention and 2 month after start of intervention

Method of measurement

TPR and weight.PSQI

2

Description

EEG waves

Timepoint

Before 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

Arak

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

City

Arak

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

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Mohsen Ebrahimi Monfared

Position

Neurologist

Other areas of specialty/work

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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