Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the effect of bright light and not having bright light on circadian rhythm changes of temperature and melatonin and fatigue in shift worker nurses

Protocol summary

Summary

In this study we assessed the effect of bright light emitted by light box on circadian rhythm of body temperature, melatonin, fatigue, and sleepiness in nurses. The subjects are selected randomly by random-number table, from shift worker nurses who are in fixed shift work, in Farabi Hospital. 44 healthy female nurses aging 20-40 will be chosen. The nurses will be divided into two groups of intervention and control. In the first stage, bright light will be emitted to the nurses in the intervention group by the light box, and bright light will not be emitted to the control group. 10,000 lux brightness range of light for thirty minutes after 4 hours from the beginning of the shift will be used. In the next stage (one month later), we will emit bright light to the control group of first stage and vice versa (cross over). As the intervention is the emitting of the light, the blindness is not possible. Main outcome measure, we will assess after intervention is changing procedure of circadian rhythm in two groups. Primary outcome measures are salivatory melatonin and body temperature and secondary outcome measures are fatigue and sleepiness. Salivatory melatonin will be measured at 4:00 am and 4:00 pm next day. Body temperature, fatigue (Visual Analogue Scale) and, sleepiness (Karolinska Scale), will be measured every hour, during next 24 hours.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016121331395N1**
Registration date: **2017-09-15, 1396/06/24**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-09-15, 1396/06/24

Registrant information

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Recruitment status

Recruitment complete

Funding source

University of social welfare and rehabilitation sciences

Expected recruitment start date

2017-02-28, 1395/12/10

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of bright light and not having bright light on circadian rhythm changes of temperature and melatonin and fatigue in shift worker nurses

Public title

The effect of bright light on circadian rhythm changes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Nurses who have fixed night shift work; Female nurses who are willing to cooperate; The age of participants should be in the range of 20 - 40 years; The work experience of participants should be between 1 - 10 years Exclusion criteria: Non- cooperation; Nurses who can not participate a session; Nurses who have the history of psychiatric diseases; Nurses who use hypnotic drugs; Nurses who have sleep disorders such as obstructive sleep apnoea

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

The method of randomization; by random-number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Social Welfare and Rehabilitation Sciences

Street address

Evin, Daneshjoo Blvd., Koodakyar St. University of Social Welfare and Rehabilitation Sciences

City

Tehran

Postal code

1985713834

Approval date

2014-12-22, 1393/10/01

Ethics committee reference number

USWR.REC.1393.205

Health conditions studied

1

Description of health condition studied

Shift work circadian rhythm disorder

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

body temperature

Timepoint

every hour during next 24 hours

Method of measurement

by Thermometer (Degrees Celsius)

2

Description

Salivary melatonin

Timepoint

at 4:00 am and 4:00 pm coming day after intervention

Method of measurement

Salivary melatonin kit (picogram/milliliter)

Secondary outcomes

1

Description

sleepiness

Timepoint

every hour during next 24 hours after intervention

Method of measurement

Karolinska Sleepiness Scale

2

Description

fatigue

Timepoint

every hour during next 24 hours after intervention

Method of measurement

Visual Analog Scale (VAS)

Intervention groups

1

Description

In case group bright light is emitted to shift work nurses

Category

Other

2

Description
In control group the light is not emitted.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Hospital
Full name of responsible person
Street address
Qazvin Square
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of University of Social Welfare and Rehabilitation Sciences
Full name of responsible person
Dr Hamidreza Khanke
Street address
Koodakyar St., Daneshjoo Blvd., Evin, University of Social Welfare and Rehabilitation Sciences ,Vice chancellor for research
City
Tehran
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of University of Social Welfare and Rehabilitation 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
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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