

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of using earplugs and eye masks during night on sleep quality, anxiety and onset of delirium in hospitalized patients in ICU at Imam Reza and Qaem hospitals in Mashhad

Protocol summary

Study aim

Determining the effect of using an earplugs and eye mask on the quality of sleep, anxiety and delirium in patients hospitalized to the intensive care unit

Design

Two arm parallel group randomised trial with blinded care and outcome assessment

Settings and conduct

This study will be conducted in ICU in Qa'im and Imam Reza hospitals in Mashhad. All doctors and nurses in intensive care units will be aware of the research process and, for further certainty, a poster that summarizes the study process will be installed in any special section where it is appropriate and visible. In beginning of study and before sleep, baseline information from patients in both groups is collected by a group of researchers who are not aware of the type of study group (control and intervention). Nurses and patients will be asked to do not inform the researchers about the use or non-use of eye masks and earplugs in order to avoid the potential impact of their knowledge on the results of the study.

Participants/Inclusion and exclusion criteria

Orientation, GCS higher than 10, hospitalization to the intensive care unit for more than 72 hours, lack of any known cognitive impairment such as dementia, dizziness and delirium at the time of admission, lack of sleep disorders such as sleep apnea, narcolepsy, chronic insomnia and restless leg syndrome

Intervention groups

At 22 o'clock for 3 nights, the nurse will be reminded to use an ear tag and eye mask for the intervention group and at 6 o'clock in the morning to help the patient remove it and, where appropriate, in the wardrobe of the patient and out of the view. The control group will not use the same nights before a specific device.

Main outcome variables

quality of sleep, anxiety and delirium

General information

Reason for update

Acronym

ICU

IRCT registration information

IRCT registration number: **IRCT20190407043189N1**

Registration date: **2019-05-25, 1398/03/04**

Registration timing: **retrospective**

Last update: **2019-05-25, 1398/03/04**

Update count: **0**

Registration date

2019-05-25, 1398/03/04

Registrant information

Name

Mahnaz Bahrami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3238 1443

Email address

bahramim@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

2015-01-21, 1393/11/01

Actual recruitment end date

2015-06-20, 1394/03/30

Trial completion date

Scientific title

The effect of using earplugs and eye masks during night on sleep quality, anxiety and onset of delirium in hospitalized patients in ICU at Imam Reza and Qaem hospitals in Mashhad

Public title

The effect of earplugs and eye masks on sleep quality, anxiety and onset of delirium in hospitalized patients in ICU

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient has Orientation GCS higher than 10 The patient is hospitalized to the intensive care unit for more than 72 hours The patient has the ability to put an earplugs and eye mask independently

Exclusion criteria:

The patient has any known hearing impairment The patient will have any known cognitive impairment such as dementia, dizziness and delirium at the time of admission The patient has any sleep disturbances such as sleep apnea, narcolepsy, chronic insomnia and restless leg syndrome at the start of the study The patient has an addiction to any drug The patient has a history of night work during the past 3 years

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **37**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignments will be made using the production of random online numbers on the relevant websites. Before the study, the researchers agreed that the first time random numbers were assigned to the control group and the second time to the intervention group. At first, the range of numbers is from 1 to 80, and then 40 random numbers for the control group and again 40 random numbers for the intervention group will be selected. The option "Not repeat numbers" will also be considered. Then the qualified patients will be numbered and will be numbered in control and intervention groups based on their number.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Nursing & Midwifery school, Ebn-sina Ave., Doctora Crossroad., Daneshgah Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2014-11-16, 1393/08/25

Ethics committee reference number

910587

Health conditions studied**1****Description of health condition studied**

Delirium

ICD-10 code**ICD-10 code description**

F05

Primary outcomes**1****Description**

quality of sleep

Timepoint

Night 1, 2 and 3 Use earplugs and eye mask

Method of measurement

Voran-Schneider-Halper's quality of sleep questionnaire

2**Description**

Anxiety

Timepoint

Night 1, 2 and 3 Use earplugs and eye mask

Method of measurement

Hospital anxiety and depression questionnaire

3**Description**

Delirium

Timepoint

Night 1, 2 and 3 Use earplugs and eye mask

Method of measurement

NEECHAM Confusion Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The nurse will put an earplugs and eye mask on the patient at 22 o'clock and leave at 6 o'clock in the morning and put in the patient's closet. This is done for 3 consecutive nights.

Category

Prevention

2**Description**

Control group: In the control group no special equipment will be used during the night.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ghaem hospital

Full name of responsible person

Simin Sharafi

Street address

Ghaem Hospital., Ahmad abad Blv., Dr. Ali Shariati Square.

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2**Recruitment center****Name of recruitment center**

Imam Raza hospital

Full name of responsible person

Simin Sharafi

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Imam Reza hospital., Imam Reza Square., Ebn-Sina Ave., Doctora Crossroad., Daneshgah Ave.

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emamreza@mums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Robab Latif Nejad Roodsari

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Hajjabadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Mahnaz Bahrami

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Master

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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

Yes - There is 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

Title and more details about the data/document

The original outcome information will be shared.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Data will be available to researchers working in academia.

Under which criteria data/document could be used

-

From where data/document is obtainable

siminsharafi68@gmail.com

What processes are involved for a request to access data/document

Send an email to siminsharafi68@gmail.com and respond within 10 business days

Comments