

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The survey of earplug effect on patient`s sleep quality in CCUs

Protocol summary

Summary

This research is conducted to determine earplug effect on hospitalized patient`s sleep quality in CCU. This cross sectional study will do by Inclusion criterias of age>18 years old, admitted during 12 md to 6pm on study day; expected length of stay in the ccu was at least 2 night; ability to read,write and understand Persian; lack of visual and auditory disorders and dementia; orientated;not using sedative drugs in past 24 hr or narcotics in 12 hr before intervention; no history of earplug use; sign a consent form and exclusion criteria of Any change in patient`s care plan, removal of earplug in less than 6 hr, rejecting the intervention. The study is designed by cross over clinical trial in which 92 sample in Heshmat therapeutic-educational center selected and were randomly allocated in two group A (46 with earplugs in first night and without it in second night) and group B(46 without earplugs in first night and with it in second night). Data were gathered by 2-part tool including researcher-made demographic/clinical questionnaire and verran-snyder halpern sleep scale. Samples will ask to wear earplug during sleep hours by cross over design in two group A and B. The research assumption is that earplug can improve sleep quality in patients hospitalized in CCU.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403031118N3**
Registration date: **2015-02-06, 1393/11/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-06, 1393/11/17

Registrant information

Name

Mojgan Baghaie Lakeh

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Social Determinants O Health Research Center, Guilan University Of Medical Science, Rasht, Iran

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The survey of earplug effect on patient`s sleep quality in CCUs

Public title

The survey of earplug effect on patient`s sleep quality in coronary care units (CCUs) of Heshmat Therapeutic-educational center- 2014

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criterias : age>18 years old; admitted during 12 md to 6pm at study day; expected length of stay in the ccu at least 2 night; ability to read,write and understand Persian language; lack of visual and auditory

disorders and dementia; orientated to time and place; lack of taking sedative drugs in past 24 hours or narcotics in 12 hours before intervention; no history of previous use of an earplug; sign a consent form to participate in the study
Exclusive criteria: Any change in patient's care for example transferring out of CCU; intentional or accidental removal of earplug in any time less than 6 hours; rejecting the intervention by samples

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Guilan University Of Medical Science

Street address

Vice T & RESEARCH ASSISTANCE, West Shahid Beheshti Blvd.

City

Rasht

Postal code

4146939814

Approval date

2014-08-20, 1393/05/29

Ethics committee reference number

2930252806

Health conditions studied

1

Description of health condition studied

Heart Disease

ICD-10 code

120-125

ICD-10 code description

Ischemic Heart Disease

Primary outcomes

1

Description

Improving patients' sleep quality

Timepoint

1-2 hr after earplug removal in the morning

Method of measurement

Veran-snyder Halpern questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

earplugs in first night and without it in second night

Category

Prevention

2

Description

without earplugs in first night and with it in second night

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Therapeutic-educational center of DR.Heshmat

Full name of responsible person

Mojgan Baghaie Lakeh

Street address

Imamkhomeini Street, Therapeutic-educational center of DR.Heshmat

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Social Determinants Of Health Research Center, Guilan University Of Medical Science, Rasht, Iran >

Full name of responsible person

Mojgan Baghaie Lakeh

Street address

Social Determinants Of Health Research Center,

Shahid Beheshti Nursing & Midwifery college,
Daneshju Street, Shahid beheshti Bolv.

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Social Determinants Of Health Research Center, Guilan University Of Medical Science, Rasht, Iran>

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**

Social Determinants Of Health Research Center, Guilan University of Medical Science, Rasht, Iran

Full name of responsible person

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Position

Faculty member

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Web page address**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