

# 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)

##### Phone

+98 13 3332 1185

##### Email address

baghaie@gums.ac.ir

##### 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 Bolv.

##### 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**

Mojgan Baghaie Lakeh

**Position**

Faculty member

**Other areas of specialty/work**

**Street address**

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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*