

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of eye masks and earplugs on sleep quality of patients with myocardial infarction CCU

#### Protocol summary

##### Summary

Sleep disturbance depends on a couple of factors such as noise, light and dark cycle disorder in cardiac care unit (CCU) that can lead to acute coronary syndrome. One of the important factors is environment. Sleep can be improved by reducing physical milieu. Although many studies have been working on sleep disorder there is little focus on removing bothering environmental features. This study was designed to compare the effects of simple and low cost devices such as eye mask and earplugs with each other on reducing the environmental factors and improving sleep in CCU patients. This study is a randomized clinical trial conducted in Afshar Hospital of Yazd in 2014. 90 Patients were randomly divided into three groups: eye mask, earplugs and both eye mask and earplugs users. VAS scale at the beginning and end of stay in ICU will be completed by the researcher.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201407127875N4**

Registration date: **2015-02-16, 1393/11/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-02-16, 1393/11/27

##### Registrant information

###### Name

Hossein Rahmani

###### Name of organization / entity

Ahvaz Jondishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1444 2865

##### Email address

rahmani.h@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research of Shahid Sadoughi University of Medical Sciences

##### Expected recruitment start date

2014-05-22, 1393/03/01

##### Expected recruitment end date

2014-09-23, 1393/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of eye masks and earplugs on sleep quality of patients with myocardial infarction CCU

##### Public title

The effect of use of eye masks and earplugs on sleep quality of patients with myocardial infarction CCU

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Minimum age 25 years; Alert and aware of the time and place; Able to respond scale, EF up to 40%. Exclusion criteria: Having chronic sleep disorders; Get sleep medications and intravenous narcotics and general anesthesia in 12 hours before the study; Hearing and vision problems.

##### Age

From **25 years** old to **90 years** old

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 90

## Randomization (investigator's opinion)

Randomized

## Randomization description

## 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

Shahid Sadoughi University of Medical Sciences

##### Street address

Shahid Sadoughi University of Medical Sciences,  
safaie, yazd

##### City

yazd

##### Postal code

#### Approval date

2014-03-18, 1392/12/27

#### Ethics committee reference number

17/1/257636/P

## Health conditions studied

### 1

#### Description of health condition studied

Sleep disorders

#### ICD-10 code

F99

#### ICD-10 code description

Mental disorder, not otherwise specified

## Primary outcomes

### 1

#### Description

sleep quality

#### Timepoint

At the beginning and end of stay in CCU

#### Method of measurement

verbal analogue scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Using earplugs and eye masks

#### Category

Prevention

### 2

#### Description

Using eye masks

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Yazd Afshar Hospital

##### Full name of responsible person

##### Street address

##### City

yazd

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Saduqi University of Medical Sciences

##### Full name of responsible person

vice chancellor for research of Shahid Saduqi  
University of Medical Sciences

##### Street address

Shahid Saduqi University of Medical Sciences , safaieh

##### City

yazd

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shahid Saduqi 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**

Shahid Saduqi University of Medical Sciences

**Full name of responsible person**

zahra fahim raouf

**Position**

master of science

**Other areas of specialty/work**

**Street address**

Shahid Saduqi University of Medical Sciences

**City**

yazd

**Postal code**

**Phone**

+98 913 354 0724

**Fax**

**Email**

sara.fraouf@yahoo.com

**Web page address**

**Phone**

+98 913 153 5531

**Fax**

**Email**

khadi20y@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Saduqi University of Medical Sciences

**Full name of responsible person**

zahra fahim raouf

**Position**

**Other areas of specialty/work**

**Street address**

**City**

**Postal code**

**Phone**

00

**Fax**

**Email**

sara.fraouf@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Saduqi University of Medical Sciences

**Full name of responsible person**

khadije dehghani

**Position**

master of science

**Other areas of specialty/work**

**Street address**

Shahid Saduqi University of Medical Sciences

**City**

yazd

**Postal code**

## 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*