

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Study on the effects of using eye mask and ear plugs on the PTSD risk level in post heart surgery in ICU patients

Protocol summary

Study aim

Determining the effect of using eye mask and ear plugs on the PTSD risk level in bedridden patients in open heart surgery care unit

Design

The present research is a clinical trial study with control group with parallel and randomize groups design of 68 patients and outcome assessment

Settings and conduct

The research environment of Shahid Rajaee Hospital in Alborz province, where open heart surgery is performed. After determining the sample size with easy sampling patients will be selected and then using the two red and white balls then patients will be divided randomly into two groups . patients under studying have an eye mask and ear plugs during the night time sleep (10 pm to 6 am), and the control group will be free of eye mask and ear plugs until the time of discharge.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1 - The patient has not history of mental illness. 2. the patient has not history of recent stress except heart surgery. 3. over 18 years old. 4. The patient has not mechanical ventilation. 5. The patient's heart surgery will be emergency. Exit criteria: 1. The patient does not want to cooperate. 2. Fear of wearing eye mask and ear plugs. 3. Have another operation after the first one .

Intervention groups

Patients who have entered the study, During night sleep (10 pm to 6 am), one group used eye mask and ear plugs, and the control group, will not use eye mask and ear plugs.

Main outcome variables

eye mask, ear plugs

General information

Reason for update

Acronym

ptsd

IRCT registration information

IRCT registration number: **IRCT20180803040683N1**

Registration date: **2018-08-05, 1397/05/14**

Registration timing: **prospective**

Last update: **2018-08-05, 1397/05/14**

Update count: **0**

Registration date

2018-08-05, 1397/05/14

Registrant information

Name

Zohreh Froughi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6001

Email address

z.froughi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study on the effects of using eye mask and ear plugs on the PTSD risk level in post heart surgery in ICU patients

Public title

Study on the effects of using eye mask and ear plugs on the PTSD risk level in post heart surgery in ICU patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The patient has not history of mental illness. The patient's heart surgery will be emergency.

Exclusion criteria:

The patient does not want to cooperate. Have another surgical operation after the first operation.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are selected by simple sampling method and then, by using two red and white balls, patients will be randomly divided to two groups

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 Qazvin University of Medical Sciences

Street address

Shahid Bahonar Blvd, Ghazvin University of Medical Sciences

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2017-05-07, 1396/02/17

Ethics committee reference number

IR.Qms.Rec.1396.70

Health conditions studied

1

Description of health condition studied

ptsd-in open heart surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Risk rate mark in the IES-R questionnaire

Timepoint

Measuring the risk of post traumatic stress two months after intervention

Method of measurement

IES-R questionnaire

Secondary outcomes

1

Description

Risk rate mark in the IES-R questionnaire

Timepoint

Two months after the intervention

Method of measurement

IES-R questionnaire

Intervention groups

1

Description

Before and the first day of surgery, , give the patient an eye mask and two ear plugs and training the procedure of using them . At night, before sleeping time mention the procedure of using instruments that we said above

Category

Prevention

2

Description

Control group: During the night time sleep, the patient does not use the eye mask and ear plugs

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid rajaee hospital

Full name of responsible person

Froughi Zohreh

Street address

Shahid beheshti Ave, Shahid rajaee hospital

City

Alborz

Province

Alborz

Postal code

3419759811

Phone

+98 26 3457 0030

Fax

+98 26 3455 4484

Email

Z.froughi@gmail.com

Web page address

<https://rajaei.abzums.ac.ir/>

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Dr. peymani, Amir

Street address

Shahid Bahonar Blvd, Ghazvin University of Medical Sciences

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3333 7006

Email

apeymani@qums.ac.ir

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

Yes

Title of funding source

Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

Person responsible for general inquiries

Contact**Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Froughi, Zohreh

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shahid Bahonar Blvd, Ghazvin University of Medical Sciences

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3333 6001

Email

Z.froughi@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Froughi, Zohreh

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shahid Bahonar Blvd, Ghazvin University of Medical Sciences Qazvin

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3333 6001

Email

Z.froughi@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Froughi, Zohreh

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shahid Bahonar Blvd, Ghazvin University of Medical Sciences Qazvin Qazvin

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3333 6001

Email

Z.froughi@gmail.com

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

Undecided - It is not yet known if there will be 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