

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the effect of using sound proof headphones during orthopedic surgery with spinal anesthesia on patients' physiological indices and length of staying in recovery room: a controlled clinical trial in selected hospitals of Isfahan in 2021

Protocol summary

Study aim

Determine the effect of using soundproof headphone on patients' physiologic indices and length of staying in recovery room in orthopedic surgeries with spinal anesthesia.

Design

Clinical trial, one side blinded, parallel group on 184 patients. In order to divide patients to intervention and control groups odd and even numbers will be allocated to patients with out paying attention to their age, sex, kind of surgery and length of it for randomization

Settings and conduct

This study is on the effect of noise on the patients' physiological parameters in orthopedic procedures and length of their stay in the recovery room. Using soundproof headphone, we try to reduce the noise heard by patients and measure its effect on patients' physiological parameters and how long they stay in the recovery room. In the intervention group, soundproof headphones are placed on the patients' ears during the operation, but the control group goes through the usual procedure. this study will be done in Kashan hospital of Isfahan. The data analyzer does not know which patient or group the information belongs to.

Participants/Inclusion and exclusion criteria

Inclusion criteria : 1. Age between 18-65 2. Operations less than 2 hours 3. Surgeries except amputation 4. Patients with normal mental condition 5. Having normal hearing Exclusion criteria: Surgeries except orthopedic surgery General anesthesia Patients with emergency

Intervention groups

In order to not hearing noise, soundproof headphone will be used for patients in intervention group and patients in control group will not get headphone and then their length of staying in recovery room and physiologic indices will be compared with each other.

Main outcome variables

Systolic blood pressure: diastolic blood pressure: heart rate: respiratory rate: oxygen saturation: length of staying in recovery room

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210612051551N1**
Registration date: **2021-11-10, 1400/08/19**
Registration timing: **prospective**

Last update: **2021-11-10, 1400/08/19**

Update count: **0**

Registration date

2021-11-10, 1400/08/19

Registrant information

Name

saeed belyad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3383 0376

Email address

saeedbelyad76@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-11, 1400/08/20

Expected recruitment end date

2021-12-21, 1400/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of using sound proof headphones during orthopedic surgery with spinal anesthesia on patients' physiological indices and length of staying in recovery room: a controlled clinical trial in selected hospitals of Isfahan in 2021

Public title
The effect of using soundproof headphone on patients' physiological indices and duration of recovery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are aged between 18-65 years
Surgeries that last less than 2 hours
Surgeries except amputation
Patients without mental illness
Having normal hearing

Exclusion criteria:

Surgeries except orthopedic surgeries
Patients with general anesthesia
Patients with emergency conditions

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **184**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Person who analyzes data doesn't know that which data belong to which group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib

City

Isfahan

Province

Isfahan

Postal code

4183634819

Approval date

2021-08-10, 1400/05/19

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.076

Health conditions studied

1

Description of health condition studied

Orthopedic surgeries with spinal anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Duration of staying in recovery room

Timepoint

When patients enter to the recovery room and when patients leave it

Method of measurement

Record time in checklist

2

Description

Systolic blood pressure

Timepoint

Before surgery, before entering recovery room, after entering recovery room, 15 minutes after entering recovery room, 30 minutes after entering recovery room

Method of measurement

Record in checklist

3

Description

Diastolic blood pressure

Timepoint

Before surgery, before entering recovery room, after entering recovery room, 15 minutes after entering recovery room, 30 minutes after entering recovery room

Method of measurement

Record in checklist

4

Description

Heart rate

Timepoint

Before surgery, before entering recovery room, after entering recovery room, 15 minutes after entering recovery room, 30 minutes after entering recovery room

Method of measurement

Record in checklist

5

Description

Respiratory rate

Timepoint

Before surgery, before entering recovery room, after entering recovery room, 15 minutes after entering recovery room, 30 minutes after entering recovery room

Method of measurement

Record in checklist

6

Description

Oxygen saturation

Timepoint

Before surgery, before entering recovery room, after entering recovery room, 15 minutes after entering recovery room, 30 minutes after entering recovery room

Method of measurement

Record in checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: using Hellberg secure 2 soundproof headphone to reduce hearing noises in patients with spinal anesthesia. the headphone will be placed on patient's ears after inducing of spinal anesthesia and it will be removed at the end of surgery when suturing is done. then we will monitor patient's physiologic indices in 5 points and also we will measure length of staying in recovery room.

Category

Diagnosis

2

Description

Control group: soundproof headphone won't be used for patients in control group and usual surgery will be done for patients.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Farhad Jalali

Street address

Kashani Ave, Navab Blvd, Isfahan City

City

Isfahan

Province

Isfahan

Postal code

4183634819

Phone

+98 13 3336 0483

Email

Saeedbelyad76@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Akram Arabi

Street address

Hezarjerib Ave, Isfahan City

City

Isfahan

Province

Isfahan

Postal code

4183634819

Phone

+98 13 3336 0483

Email

Aarabi@nm.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Saeed Belyad

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

surgical technology

Street address

Keshavarzi Blvd., Keshavarzi Sq. Kosar dormitory

City

Isfahan

Province

Isfahan

Postal code

4183634819

Phone

+98 13 3336 0483

Email

saeedbelyad76@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Akram Arabi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Hezarjerib Ave

City

Isfahan

Province

Isfahan

Postal code

4183634819

Phone

+98 13 3336 0483

Email

Aarabi@nm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Saeed Belyad

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Operating room

Street address

No. 12, Keshavarzi Ave., Keshavarzi Blvd., Isfahan

City

City

Isfahan

Province

Isfahan

Postal code

4183634819

Phone

+98 13 3383 0376

Fax**Email**

Saeedbelyad76@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

All data including data related to main variables like "length of staying in recovery room" and "mean of physiologic indices" and also background variables like kind of surgery, age and sex of patients will be published after unrecognizing patients.

When the data will become available and for how long

Six months after gathering results

To whom data/document is available

Researchers working in universities will get access to data.

Under which criteria data/document could be used

Using data for : 1. Therapeutic goals 2. research goals

From where data/document is obtainable

Saeed Belyad 0098 937 2580188

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

Sending a request by calling and providing evidence for use in research or treatment and receiving data in less than a week

Comments