

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 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: heat 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**