

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Effect of white noise versus control group on the pain and anxiety of patients undergoing extracorporeal shock wave lithotripsy: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of white noise versus control group on the pain and anxiety of patients during extracorporeal shock wave lithotripsy

##### Design

This is a randomized clinical trial study with a control group, with parallel design, without the possibility of blinding, phase 3, in which 60 eligible patients will be randomly assigned to two intervention and control groups by lottery method.

##### Settings and conduct

This study will be conducted at the Beheshti Hospital in Hamadan city, involving 60 eligible patients undergoing extracorporeal shock wave lithotripsy. The patients will be randomly assigned in parallel design to the intervention and control groups through the drawing of lots. However, it should be noted that blinding is not feasible in this trial.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 20 to 50 years Indications for extracorporeal shock wave lithotripsy Being literate  
Exclusion criteria: Having colicky kidney pains before lithotripsy Auditory disorder History of anxiety or mental disorder

##### Intervention groups

Intervention group: Routine care during extracorporeal shock wave lithotripsy in addition to playing white noise (including the sound of nature such as the sound of birds and the sound of water) with a frequency lower than 85 dB for 45 minutes through headphones Control group: Just routine care during extracorporeal shock wave lithotripsy

##### Main outcome variables

Pain score; anxiety score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N497**

Registration date: **2024-02-14, 1402/11/25**

Registration timing: **prospective**

Last update: **2024-02-14, 1402/11/25**

Update count: **0**

##### Registration date

2024-02-14, 1402/11/25

##### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-03-05, 1402/12/15

##### Expected recruitment end date

2024-06-04, 1403/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effect of white noise versus control group on the pain and anxiety of patients undergoing extracorporeal shock wave lithotripsy: a randomized clinical trial

**Public title**

Effect of white noise versus control group on the pain and anxiety of patients undergoing extracorporeal shock wave lithotripsy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 20 to 50 years Indications for extracorporeal shock wave lithotripsy Being literate

**Exclusion criteria:**

Having colicky kidney pains before lithotripsy Auditory disorder History of anxiety or mental disorder

**Age**

From **20 years** old to **50 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random allocation of patients to intervention and control groups by lottery. For this purpose, we prepare two sheets, write "intervention" on one and "control" on the other. Then, with each patient's visit, one of the sheets is randomly taken and the patient is assigned to the intervention or control group.

**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 Hamadan University of Medical Sciences

**Street address**

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Fahmideh  
Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Approval date**

2024-02-10, 1402/11/21

**Ethics committee reference number**

IR.UMSHA.REC.1402.687

**Health conditions studied****1****Description of health condition studied**

Anxiety

**ICD-10 code**

F06.4

**ICD-10 code description**

Anxiety disorder due to known physiological condition

**2****Description of health condition studied**

Pain

**ICD-10 code**

G89.1

**ICD-10 code description**

Acute pain, not elsewhere classified

**Primary outcomes****1****Description**

Pain score

**Timepoint**

Before the intervention and immediately after that

**Method of measurement**

using the Visual Analog Scale (VAS)

**2****Description**

Anxiety score

**Timepoint**

Before the intervention and immediately after that

**Method of measurement**

Using the Spielberger Anxiety Questionnaire

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: Routine care during extracorporeal shock wave lithotripsy in addition to playing white noise (including the sound of nature such as the sound of birds and the sound of water) with a frequency lower than 85 dB for 45 minutes through headphones

### Category

Treatment - Devices

## 2

### Description

Control group: Just routine care during extracorporeal shock wave lithotripsy

### Category

N/A

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Beheshti Hospital in Hamadan city

#### Full name of responsible person

Zahra Karimi Vafa

#### Street address

Beheshti Hospital, Eram Ave.

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Phone

+98 81 3838 0283

#### Email

zahrakarimivafa@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Dr. Reza Shokoohi

#### Street address

Hamadan University of Medical Sciences, Fahmideh Ave

#### City

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#### Phone

+98 81 3838 0717

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info.research@umsha.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

#### Full name of responsible person

Zahra Karimi Vafa

#### Position

Student of Nursery

#### Latest degree

Master

#### Other areas of specialty/work

Nursery

#### Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Fahmideh Ave.

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Dr. Arezoo Karampoorian

#### Position

Health in Emergency and Disasters Specialist

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Health in Emergency and Disaster

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karampor1@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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poorolajal@umsha.ac.ir

## 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