# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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**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**
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**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
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Beheshti Hospital, Eram Ave.
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## Sponsors / Funding sources

**1**

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Hamedan University of Medical Sciences
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**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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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