# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Effect of allowed favorite music versus control group on the pain and anxiety of patients under extracorporeal shock wave lithotripsy: a randomized control trial

## Protocol summary


**Study aim**
To assess the effect of allowed favorite music versus control group on the pain and anxiety of patients under extracorporeal shock wave lithotripsy

**Design**
This is a randomized clinical trial with a control group with parallel groups without blinding, in which 60 eligible patients will be randomly assigned to the intervention and control groups using block randomization.

**Settings and conduct**
This study will be conducted at the Alborz Hospital in Karaj city, involving 60 eligible patients under extracorporeal shock wave lithotripsy. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not feasible in this trial.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age of 18 to 65 years Kidney stones Healthy hearing Literacy Ability to speak Persian Exclusion criteria: Renal colic pain before lithotripsy Previous history of lithotripsy Use of anti-anxiety drugs, narcotics, painkillers Neurological and psychiatric diseases

**Intervention groups**
Intervention group: Routine care before extracorporeal lithotripsy plus playing favorite music (including classical, pop, etc.) using Tesco Bluetooth headphones, model TH-5376, with a frequency of less than 85 dB for 15 to 30 minutes before extracorporeal lithotripsy Control group: Only routine care before extracorporeal lithotripsy

**Main outcome variables**
Primary outcome: Pain intensity; Anxiety score


## General information

**Reason for update**

**Acronym**


**IRCT registration information**
IRCT registration number: **IRCT20120215009014N567**
Registration date: **2025-08-04, 1404/05/13**
Registration timing: **prospective**

Last update: **2025-08-04, 1404/05/13**
Update count: **0**

**Registration date**
2025-08-04, 1404/05/13



**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**
2025-08-23, 1404/06/01

**Expected recruitment end date**
2025-10-23, 1404/08/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty


**Scientific title**

Effect of allowed favorite music versus control group on the pain and anxiety of patients under extracorporeal shock wave lithotripsy: a randomized control trial

**Public title**
Effect of allowed favorite music versus control group on the pain and anxiety of patients under extracorporeal shock wave lithotripsy
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age of 18 to 65 years Kidney stones Healthy hearing Literacy Ability to speak Persian
**Exclusion criteria:**
Renal colic pain before lithotripsy Previous history of lithotripsy Use of anti-anxiety drugs, narcotics, painkillers Neurological and psychiatric diseases
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.
**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**
Research Ethics Committees of Asadabad School of Medical Sciences
**Street address**
Vice-chancellor for Research and Technology, Asadabad School of Medical Sciences, Rafsanjani Ave.
**City**
Asadabad
**Province**
Hamadan
**Postal code**
6541843189
**Approval date**
2025-07-02, 1404/04/11
**Ethics committee reference number**
IR.ASAUMS.REC.1404.003

## 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**
Renal colic pain
**ICD-10 code**
N23
**ICD-10 code description**
Unspecified renal colic

## Primary outcomes

### 1

**Description**
Pain intensity
**Timepoint**
Before the start of lithotripsy and immediately after the end of lithotripsy
**Method of measurement**
Using the Visual Analog Scale (VAS)

### 2

**Description**
Anxiety score
**Timepoint**
Before the start of lithotripsy and immediately after the end of lithotripsy
**Method of measurement**
Using the Spielberger Anxiety Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Routine care before extracorporeal lithotripsy plus playing favorite music (including classical, pop, etc.) using Tesco Bluetooth headphones, model TH-5376, with a frequency of less than 85 dB for 15 to 30 minutes before extracorporeal lithotripsy
**Category**
Treatment - Other

### 2

**Description**
Control group: Only routine care before extracorporeal lithotripsy
**Category**
N/A

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Alborz Hospital in Karaj city
**Full name of responsible person**
Daniel Moradi
**Street address**
Alborz Hospital, Parastar Ave.
**City**
Karaj
**Province**
Alborz
**Postal code**
6541843189
**Phone**
+98 81 3313 2015
**Email**
daniel.moradi7678@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Asadabad University of Medical Sciences
**Full name of responsible person**
Sasan Navkhasi
**Street address**
Vice-chancellor for Research and Technology, Asadabad School of Medical Sciences, Rafsanjani Ave.
**City**
Asadabad
**Province**
Hamadan
**Postal code**
6541843189
**Phone**
+98 81 3313 2015
**Email**
n.heydari@asaums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Asadabad 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**
Asadabad University of Medical Sciences
**Full name of responsible person**
Daniel Moradi
**Position**
Master of Science in Nursing
**Latest degree**
Master
**Other areas of specialty/work**
Nursery
**Street address**
Asadabad School of Medical Sciences, Rafsanjani Ave.
**City**
Asadabad
**Province**
Hamadan
**Postal code**
6541843189
**Phone**
+98 81 3313 2015
**Email**
daniel.moradi7678@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Asadabad University of Medical Sciences
**Full name of responsible person**
Daniel Moradi
**Position**
Master of Science in Nursing
**Latest degree**
Master
**Other areas of specialty/work**
Nursery

**Street address**
Asadabad School of Medical Sciences, Rafsanjani Ave.
**City**
Asadabad
**Province**
Hamadan
**Postal code**
6541843189
**Phone**
+98 81 3313 2015
**Email**
daniel.moradi7678@gmail.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
**Street address**
School of Public Health, Hamadan University of Medical Sciences, Fahmideh Ave
**City**
Hamadan
**Province**
Hamadan
**Postal code**
6517838695
**Phone**
+98 81 3838 0090
**Email**
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