Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effect of music and anti-stress ball on pain and hemodynamic parameters in patients undergoing Extracorporeal shockwave lithotripsy (ESWL): Clinical trial

Protocol summary

Study aim

To compare the effects of using music and stress ball on pain levels and hemodynamic parameters in patients undergoing extracorporeal shock wave lithotripsy (ESWL). To determine and compare the mean pain scores before and after the intervention among the music, stress ball, and control groups in patients undergoing ESWL. To determine and compare the mean hemodynamic parameters(systolic blood pressure, diastolic blood pressure, heart rate, respiratory rate, and oxygen saturation) before and after the intervention among the music, stress ball, and control groups in patients undergoing ESWL.

Design

An unblinded, randomized, parallel-group controlled clinical trial will be conducted in 114 patients. Randomization will be performed using the online randomization service Sealed Envelope Ltd.

Settings and conduct

Razi University Hospital in Rasht

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 18 years or older, No hearing impairment, No current use of cardiovascular medications affecting blood pressure and heart rate, Provided informed consent to participate in the study. Exclusion Criteria: Use of any analgesic medications, muscle relaxants, psychotropic drugs, corticosteroids, and aspirin.

Intervention groups

Music intervention group: Participants undergoing (ESWL) will listen to calming nature sounds through headphones at a comfortable volume during the entire procedure and receive standard care according to the institution's protocol . Stress ball intervention group: Participants undergoing (ESWL) will be provided with two soft, pliable stress balls to squeeze during the entire procedure and receive standard care according to the institution's protocol. Control group: Participants undergoing (ESWL) receive standard care according to the institution's protocol.

Main outcome variables

Pain, Hemodynamic parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231104059953N1**
Registration date: **2024-10-19, 1403/07/28**
Registration timing: **prospective**

Last update: **2024-10-19, 1403/07/28**
Update count: **0**

Registration date

2024-10-19, 1403/07/28

Registrant information

Name

Maryam khoshbakht-Pishkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3355 5056

Email address

khoshbakht3897@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-29, 1403/09/09

Expected recruitment end date

2025-02-27, 1403/12/09

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of music and anti-stress ball on pain and hemodynamic parameters in patients undergoing Extracorporeal shockwave lithotripsy (ESWL): Clinical trial

Public title
Comparison of the effects of music and stress balls on pain levels and hemodynamic parameters during extracorporeal shock wave lithotripsy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 years or older no hearing impairment current use of cardiovascular medications affecting blood pressure and heart rate informed consent to participate in the study
Exclusion criteria:
Use of pain relievers Use of muscle relaxants Use of psychotropic drugs Use of corticosteroids Use of aspirin
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **114**
Randomization (investigator's opinion)
Randomized
Randomization description
All eligible patients will be randomly assigned to one of three groups (music, stress ball, or control) using a block randomization procedure with a block size of six. This will result in an equal allocation ratio of 1:1:1 among the groups. The first six patients will form a block, and then two patients will be randomly assigned to each group. The order of the groups within each block will be randomized. A sealed envelope system (SNOSE) will be used to generate the randomization list. To determine group allocation, opaque, sealed envelopes containing the intervention type will be used.
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 Guilan university of medical sciences
Street address
Nursing and Midwifery school, Daneshjo St., Shahid Beheshti Blvd.
City
Rasht
Province
Guilan
Postal code
41469-39814
Approval date
2024-09-25, 1403/07/04
Ethics committee reference number
IR.GUMS.REC.1403.267

Health conditions studied

1

Description of health condition studied
Kidney stone
ICD-10 code
N20.0: Cal
ICD-10 code description
Calculus of kidney and ureterIncl.: calculous pyelonephritisExcl.: with hydronephrosis (N13.2)

Primary outcomes

1

Description
Pain score based on Visual Analogue Scale
Timepoint
Immediately before the start of extracorporeal shock wave lithotripsy (ESWL) and intervention and right after ESWL and intervention
Method of measurement
Pain Visual Analogue Scale assessment instrument

Secondary outcomes

1

Description
Hemodynamic parameters
Timepoint
Right before the start of ESWL and interventions and right after finishing ESWL and intervention.
Method of measurement
By means of a monitoring device

Intervention groups

1

Description
Control group: receiving care as per the center's treatment guidelines.
Category
Treatment - Other

2

Description
Intervention group: receiving music
Category
Treatment - Other

3

Description
Intervention group: receiving stress ball
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi university hospital
Full name of responsible person
Maryam Khoshbakht-Pishkhani
Street address
Nursing and Midwifery school, Daneshjo St., Shahid Beheshti Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Maryam Khoshbakht-Pishkhani
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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
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Maryam Khoshbakht-Pishkhani
Position
Assistant Professor of Nursing, Department of Critical care Nursing, School of Nursing and Midwifer
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Full name of responsible person
Maryam Khoshbakht-Pishkhani

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Person responsible for updating data

Contact
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student
Latest degree
Bachelor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
Upon completion of the study, only a subset of the data, specifically information pertaining to the primary outcome, will be shared.
When the data will become available and for how long
Access will be granted for a period of six months starting from the date of publication
To whom data/document is available
Researchers affiliated with academic institutions
Under which criteria data/document could be used
The data are restricted to use in citing the study outcomes
From where data/document is obtainable
Kindly refer to the email of the person in charge
What processes are involved for a request to access data/document
Initially, the applicant should email the responsible party, stating their reasons for requesting data access and providing a copy of their research ethics code. The responsible party will review the request and provide a response within 10 business days.
Comments