Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Impact of music therapy on pain and anxiety of patient undergoing Extra corporeal Shock Wave Lithography

Protocol summary

Study aim
Impact of music therapy on pain and anxiety of patient undergoing Extracorporeal Shock Wave Lithotripsy

Design
Randomized clinical trial with a control group, convenience sampling, one-way blind, sample size base on pilot study.

Settings and conduct
Place: ESWL unit, Imam Ali Hospital in Bojnourd All patients with urinary stones between 18 and 60 years old referred for ESWL were enrolled to study. Randomization-based on AB blocks and sample size determination with a pilot study (10 patients in each group) patients have placed in groups A (music therapy), B (control). In all two groups, prior to ESWL, anxiety measured by the visual analog scale and hemodynamic parameters will be recorded. In Group A: headphones are placed on the patient's head in play mode . Group B: headphones are placed on the patient's head in silent mode. In all cases, the pain will be measured by numerical rating scale every 10 minutes and after the lithotripsy procedure. Hemodynamic parameters will be recorded initially and then every 10 minutes and at the end of the procedure and anxiety will be recorded at the end of lithotripsy. If the patient was restless during lithotripsy any time or pain score was above 7, with the approval of anesthesiologist, the routine care of the center is performed and the patient is excluded.

Participants/Inclusion and exclusion criteria
Patient that candidate for Extra corporeal Shock Wave Lithography

Intervention groups
Music therapy

Main outcome variables
Pain, anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201511026776N2**
Registration date: **2015-12-24, 1394/10/03**
Registration timing: **prospective**

Last update: **2018-09-12, 1397/06/21**
Update count: **1**

Registration date
2015-12-24, 1394/10/03

Registrant information

Name
Tooba Hoseini Azizi
Name of organization / entity
Mashhad University of Medical Science
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Recruitment status
Recruitment complete

Funding source
North Khorasan University of Medical Sciences

Expected recruitment start date
2018-11-20, 1397/08/29

Expected recruitment end date
2019-04-18, 1398/01/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Impact of music therapy on pain and anxiety of patient

undergoing Extra corporeal Shock Wave Lithography

Public title
Impact of music therapy on anxiety and pain of patient undergoing Extra corporeal Shock Wave Lithography
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
18-60 years old Ability for reading and writing Candidate for ESWL No history of ESWL
Exclusion criteria:
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Series of the random number equal to the half number of samples will be selected from a random numbers table. If the random number will between 0 and 4, phrase AB and if between 5 and 9, phrase BA will be written next to each other, then numbered and, according to the entry, the patients will be assigned into one of groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
Headphone put on the ears of Participants in both music therapy and control groups. Music will only be played in music therapy groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
North Khorasan University of Medical Sciences
Street address
North Khorasan
City
Bojnourd
Province
North Khorasan
Postal code
9414635665
Approval date
2015-10-05, 1394/07/13
Ethics committee reference number
ir.nkums.rec.1394.34

Health conditions studied

1

Description of health condition studied
Urinary stones
ICD-10 code
N20
ICD-10 code description
Calculus of kidney and ureter

Primary outcomes

1

Description
Pain
Timepoint
Each 10 min during and after Procedure
Method of measurement
Numeric pain rating scale

2

Description
Anxiety
Timepoint
Before and after procedure
Method of measurement
Anxiety numerical visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Music therapy: Before entering the ESWL room, the patient's anxiety will measured by the visual analog scale, after transfer the patient on ESWL bed, blood pressure (systole and diastole and mean arterial blood pressure), heart rate and respiration rate, arterial oxygen saturation measured and recorded. The patient will given a position depending on the location of the urinary stones. By controlling with ultrasound, the focus of the device is adjusted to the stone. Before the procedure begins, the headphones are placed on the patient's head and the music starts playing. During the ESWL process, whenever the patient becomes restless or in the examination of a pain score of more than 7, the routine care of the center will be performed. In this case, the patient will be excluded from the study. With the start of the procedure, the pain is measured every 10 minutes

and at the end of the procedure with a numerical grading scale. The mean arterial pressure, heart rate and respiratory rate per minute, and arterial oxygen saturation are monitored at the beginning and then every 10 minutes at the end of the procedure. Anxiety is measured and recorded at the end of the procedure. Anxiety and pain measurement will be measured by a radiologist at the center. The total ESWL time, severity and number of shock, the total dose of the analgesic and anti-anxiety medication received, the length of the patient's stay in recovery will be recorded for each patient.

Category

Treatment - Other

2

Description

Control group: Music therapy: Before entering the ESWL room, the patient's anxiety will measured by the visual analog scale, after transfer the patient on ESWL bed, blood pressure (systole and diastole and mean arterial blood pressure), heart rate and respiration rate, arterial oxygen saturation measured and recorded. The patient will given a position depending on the location of the urinary stones. By controlling with ultrasound, the focus of the device is adjusted to the stone.Before starting the procedure to cover the intervention, headphones are placed on the patient's head without music playing. During the ESWL process, whenever the patient becomes restless or in the examination of a pain score of more than 7, the routine care of the center will be performed. With the start of the procedure, the pain is measured every 10 minutes and at the end of the procedure with a numerical grading scale. The mean arterial pressure, heart rate and respiratory rate per minute, and arterial oxygen saturation are monitored at the beginning and then every 10 minutes at the end of the procedure. Anxiety is measured and recorded at the end of the procedure. Anxiety and pain measurement will be measured by a radiologist at the center. The total ESWL time, severity and number of shock, the total dose of the analgesic and anti-anxiety medication received, the length of the patient's stay in recovery will be recorded for each patient.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital. ESWL center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Dr Hojat

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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

Bojnourd 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

North Khorasan University of Medical Sciences

Full name of responsible person

Tooba Hoseini Azizi

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable