Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparing the effect of distraction of thought and prayer on pain and anxiety in patients with extracorporeal shock wave lithotripsy(ESWL)

Protocol summary

Study aim
Comparison the effect of two ways of distraction and praying on the severity of pain and anxiety in patients undergoing ESWL

Design
This study is a randomized clinical trial that will be carried out after obtaining the necessary permissions from the Assistant and Technology Department, the Ethics Committee and the competent authorities at the Ayatollah Kashani Hospital in Shahrekord. Patients with inclusion criteria will be divided into three groups (recipient, prayer, and control), after obtaining the informed consent of the study (written), by available and random allocation method. Became During the fracture process, after the routine treatment, the McGill and McGill pain questionnaires and the Spielberger questionnaire will be completed. Then, in the deviant group, in addition to routine drug therapy, the nature of the sound accompanied by the beautiful nature of the scenery, The headphones and TV will be used. In the prayer group, in addition to routine drug therapy, the patient will be repeatedly prayed for "Allaham Sul Ali Mohammad and Al-Muhammad". The control group will receive routine care.

Settings and conduct
Exterminating ESWL department of Ayatollah Kashani Hospital, Shahrekord

Participants/Inclusion and exclusion criteria
Candidates for crushing; reading and writing literacy; age over 18 years old; patient's awareness of the person, time, place; absence of anti-anxiety drugs in the last 24 hours; absence of underlying diseases causing pain or anxiety; lack of mental illness or mental retardation; lack of Blood anticoagulant; lack of anti epileptic drugs, antidepressants; no previous history of depression and anxiety and severe stressful events in life during the past 6 months; lack of thyroid disease

Intervention groups
distraction and prayer

Main outcome variables
Pain; anxiety; distraction of thought and prayer

General information

Reason for update

Acronym
ESWL

IRCT registration information
IRCT registration number: **IRCT20170122032101N3**
Registration date: **2019-04-17, 1398/01/28**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-17, 1398/01/28**
Update count: **0**

Registration date
2019-04-17, 1398/01/28

Registrant information

Name
Haydeh Heidari

Name of organization / entity
Medical University

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-10, 1397/11/21

Expected recruitment end date
2019-05-05, 1398/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of distraction of thought and prayer on pain and anxiety in patients with extracorporeal shock wave lithotripsy(ESWL)

Public title
Comparing the effect of distraction of thought and prayer on pain and anxiety in patients with extracorporeal shock wave lithotripsy(ESWL)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidates for ESWL Having reading and writing skills No anti-anxiety drugs received in the last 24 hours, The absence of underlying illnesses that cause pain or anxiety Lack of active mental illness or mental retardation Absence of blood anticoagulant No previous history of depression and anxiety and severe stressful events in life over the last 6 months, Not having thyroid disease Awareness of the patient to the person, time, place
Exclusion criteria:
Unwillingness to continue to participate in research Children UTI Coagolopathy Pregnancy Patients once studied by us
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done by blocking method based on group variables and a history of rock breakdown. The number of blocks is obtained by multiplying the states of each variable. The age group of five states (18-25, 35-25, 45-35, 55-45, and over 55 years old) and a history of rock breakdown of two states (previous history of rock formation, previous history of rock It will not break). A total of 10 blocks will be determined. The capacity of each block is obtained by dividing the total sample size by the number of blocks, each block having capacity for 18 people. Since the study consists of three groups, each block of 18 people will be divided into three groups of six. In order to allocate each block to the test group one (deviation), test two (prayer) and control, the researcher first will determine, based on the patient information, which block belongs to each patient, then from the file number Patient, patients whose case numbers were 2-0, in the test group one (deviant), patients whose file numbers were between 5-3, in the test group two (Prayer) and patients whose file numbers are 6 to 6, will be assigned to the control group and patients with a file number of 9 will be excluded from participation in the study. .
Blinding (investigator's opinion)
Single blinded
Blinding description
Samples do not know how to enter the groups and they are blindly entered into an intervention or control group
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrekord University of Medical Sciences
Street address
No 10, KashaniAve., Shahrekord city
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Province
Chahar-Mahal-va-Bakhtiari
Postal code
8814814776
Approval date
2019-02-19, 1397/11/30
Ethics committee reference number
IR.SKUMS.REC.1397.282

Health conditions studied

1

Description of health condition studied
extracorporeal shock wave lithotripsy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain
Timepoint
Before and after intervention
Method of measurement
MC GILL

Secondary outcomes

1

Description
Anxiety
Timepoint
Before and after intervention
Method of measurement
Spill Berger

Intervention groups

1

Description
First, during the process of ESWL after the routine treatment, the McGill pain questionnaire and the 20 questions of the Espill Berger questionnaire, which is related to the apparent anxiety, will be completed, and then in the group receiving thedistraction, On routine drug therapy, nature sounds accompanied by beautiful nature images will be used to relieve pain and anxiety. Then again, the McGill pain questionnaire and the anxiety section of the Spielberger Anxiety Inventory will be completed again in all three groups.
Category
Treatment - Other

2

Description
First, during routine process, after the routine treatment, the McGill Pain Questionnaire and the 20-item Spielberger questionnaire, which is related to the apparent anxiety, will be completed. In the group receiving prayer, in addition to drug therapy, the patient will repeatedly mention the prayers of "Allah, peace be upon him, Muhammad and Al-Muhammad". The control group will receive routine care. In all three groups, if the pain is expressed, the patient will receive the repeated doses and the dose and the frequency of duplication of the patient. Then again, the McGill pain questionnaire and the anxiety section of the Spielberger Anxiety Inventory will be completed again in all three groups.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
shahrekord university of medical sciences,Research Deputy
Grant code / Reference number
2929
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person

Haydeh Heidari

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assisstant professor
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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
Article
When the data will become available and for how long
2 years
To whom data/document is available
All authors
Under which criteria data/document could be used
For using of result
From where data/document is obtainable
Haydeh Heidari
What processes are involved for a request to access data/document
E mail
Comments