

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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Iran (Islamic Republic of)

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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 Coagulopathy 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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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 the distraction, 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

Shahre-kord University of Medical Sciences

Full name of responsible person

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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

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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