Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assessing The effect of provision of information by video and lecture before Extracorporeal Shock Wave Lithotripsy on patient anxiety and comfort

Protocol summary

Study aim
Determination The effect of provision of information by video and lecture before Extracorporeal Shock Wave Lithotripsy on patient anxiety and comfort

Design
clinical trial with a parallel group design of 122patients, Randomization by blocking method

Settings and conduct
This research is performed at Baharloo Hospital in Tehran First, the background and demographic information of the patients were collected and Saliva samples taken and Physiological indicators including respiratory rate, pulse rate and blood pressure are collected before awareness and Patients complete Spielberger Manifest Anxiety Questionnaire and Kolkaba General Comfort Questionnaire Then, in the intervention group, awareness is performed And again aliva samples taken and Physiological indicators collected and Patients complete Questionnaire. The control group receives the information according to the previous routine of the ward.

Participants/Inclusion and exclusion criteria
Candidate patients for extracorporeal lithotripsy in Baharloo hospital with Inclusion criteria Any dissatisfaction with participating in the study

Intervention groups
To the intervention group in order to inform before the operation, in the morning of the operation Researcher With face-to-face speeches in groups of 3-4 in the conference room talks about Information included Introduction of urinary tract, how to create kidney stones and its types, symptoms, method of prevention, diagnosis and treatment, extracorporeal lithotripsy procedure, complications, care and postoperative follow-up and then play a video that shows Location, procedure, place of postoperative hospitalization This intervention takes 30 minutes Patients' questions are also answered for 30 minutes. The control group receives the information according to the previous routine.

Main outcome variables
Possibility of reducing anxiety and increasing preoperative comfort

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200827048546N1**
Registration date: **2020-09-06, 1399/06/16**
Registration timing: **prospective**

Last update: **2020-09-06, 1399/06/16**
Update count: **0**

Registration date
2020-09-06, 1399/06/16

Registrant information

Name
saeedeh azizi mahkooyeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 3613 4292

Email address
saeedeh.azizi2013@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-22, 1399/08/01

Expected recruitment end date
2021-03-20, 1399/12/30

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

Scientific title
Assessing The effect of provision of information by video and lecture before Extracorporeal Shock Wave Lithotripsy on patient anxiety and comfort

Public title
Assessing The effect of provision of information on patient anxiety and comfort in Extracorporeal Shock Wave Lithotripsy
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Patient with urinary stone Disease and ESWL candidate Willingness to cooperate in the project Ages 18 to 65 years The first experience of ESWL Ability to read and write No membership in the treatment team Lack of vision and hearing problems Do not take medications that reduce or increase cortisol like Corticosteroids, anticonvulsants, insulin Do not use sedatives and anti-anxiety drugs before the intervention
Exclusion criteria:
Any patient dissatisfaction during the research Any acute problems at the time of the study
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: **122**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling in this research is done in two stages.In the first step, the samples are selected by the Convenience Sampling method. In the second stage, the allocation of samples to the two groups of intervention and control is done randomly and by blocking method; The letter A is considered for the intervention group and the letter B for the control group. Then we write all the combinations of the letters A, A,and B ,B, which are 6 different combinations, on 6 cards: 1. AABB 2. ABBA 3. ABAB 4. BAAB 5. BABA 6. BBAA Then, from digits 1 to 6, a digit is randomly selected(With the help of a table of random numbers or patient number one is asked to choose a card at random.) For example, if the digit 2 is selected This means that the first person is in the intervention group and the next two people are in the control group and the fourth person is in the intervention group and This Process continues until the sample size reaches the quorum.
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
Ethics committee of Nursing And Midwifery and Rehabilitation School, Tehran University Of Medical S
Street address
Tehran Province, Tehran, District 6, Nosrat St
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2020-08-23, 1399/06/02
Ethics committee reference number
IR.TUMS.FNM.REC.1399.088

Health conditions studied

1

Description of health condition studied
Urinary tract stones
ICD-10 code
N20.9
ICD-10 code description
Urinary calculus, unspecified

2

Description of health condition studied
Extracorporeal Shock Wave Lithotripsy
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Anxiety
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

4

Description of health condition studied
Comfort
ICD-10 code
ICD-10 code description

5

Description of health condition studied
Cortisol
ICD-10 code
ICD-10 code description

6

Description of health condition studied
Physiological indicators
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Anxiety score in Spielberger's anxiety questionnaire
Timepoint
Completion of the questionnaire before the intervention and after the awareness
Method of measurement
Spielberger Anxiety Questionnaire

2

Description
Measuring anxiety with salivary cortisol levels
Timepoint
Before the intervention and after the awareness
Method of measurement
Saliva sample in the amount of 3 to 5 cc

3

Description
Anxiety level by measuring the number of breaths, pulse rate and blood pressure
Timepoint
Before the intervention and after the awareness
Method of measurement
Count the number of breaths and pulses per minute And measuring blood pressure with a mercury sphygmomanometer

4

Description
Comfort score on the Kolkaba General Comfort Questionnaire
Timepoint
Before the intervention and after the awareness
Method of measurement
Kolkaba General Comfort Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: To the intervention group in order to inform before the operation, in the morning of the operation Researcher With face-to-face speeches in groups of 3-4 in the conference room talks about Information included Introduction of urinary tract, how to create kidney stones and its types, symptoms, method of prevention, diagnosis and treatment, extracorporeal lithotripsy procedure, complications, care and postoperative follow-up and then play a video that shows Location, procedure, place of postoperative hospitalization This intervention takes 30 minutes Patients' questions are also answered for 30 minutes.
Category
Other

2

Description
Control group: The control group receives the information according to the previous routine.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Baharloo hospital
Full name of responsible person
Saeedeh Azizi Mahkooyeh
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Tehran, Rahahan Square, Baharloo hospital
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12299
Phone
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person
Mojdeh Navidhamidi

Street address
Tehran Province, Tehran, District 6, Nosrat St

City
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Province
Tehran

Postal code
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Fax
+98 21 6642 7255

Email
fnm-researchdeputy@tums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Saeedeh Azizi Mahkooyeh

Position
Master student of medical Surgical Nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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No. 12, Vali Asr avenue, Bagherabadd, Varamin

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Position
Master student of Medical Surgical Nursing

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Will be published

When the data will become available and for how long

3 months after the publication of the results

To whom data/document is available

For all

Under which criteria data/document could be used

To increase knowledge in this field

From where data/document is obtainable

saeedeh.azizi2013@gmail.com

What processes are involved for a request to access data/document

It will be done as soon as possible after requesting by email.

Comments