

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 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

##### **Street address**

Tehran, Rahahan Square, Baharloo hospital

##### **City**

Tehran

##### **Province**

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##### **Postal code**

12299

##### **Phone**

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##### **Fax**

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##### **Email**

baharloo@sina.tums.ac.ir

## **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**

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**Postal code**

1419733171

**Phone**

+98 21 6692 4411

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**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**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

Master student of Medical Surgical Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran 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**

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**