

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The Efficacy of Visualization on Preoperative Anxiety in Patients Undergoing Endoscopic Urology Surgery

Protocol summary

Study aim

Effect of Visualization on Preoperative Anxiety in Patients Candidate for Urology Endoscopic Surgery

Design

This study is an interventional study in a two-group randomized clinical trial including control group and intervention group. In this study, 120 patients with 30 intervention and 30 control (TUL & TURBT) patients, respectively, were all eligible for inclusion. They will be randomly assigned to four blocks by random blocking method and will participate in the study.

Settings and conduct

The research setting is the Urology Department of Bahonar Hospital of Kerman. All patients who have a definitive diagnosis of a bladder tumor or urinary stones from a specialist doctor's referral to the Urology Department and who meet the inclusion criteria are eligible for inclusion. The intervention is intuitive through visual and auditory animation. The night before surgery, the researcher identifies eligible patients for inclusion in the study and will enter the study if they score above 43 on the STAI scale. Patients identified in the intervention group will then see the surgical animation in the group conference room. After the intervention and one hour before surgery, the questionnaire will be completed again. In this single-blind study, sampling will be done by people who are unaware of the nature of the groups and can also be randomly selected by someone who is unaware of the groups.

Participants/Inclusion and exclusion criteria

Patients undergoing Trans Urethral Lithotripsy (TUL) or Trans Urethral Resection of Bladder (TURBT) surgery
Ability to communicate in Persian
Age over 20 years
Get a minimum score of 43 on the State-Trait Anxiety Inventory (STAI) scale in two sub-scales (explicit and hidden)

Intervention groups

Intervention: In this study, intuitive visual and auditory

animation is used. Control: The control group only receives routine care.

Main outcome variables

Anxiety, Visualization, Age

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190413043251N1**

Registration date: **2020-06-14, 1399/03/25**

Registration timing: **retrospective**

Last update: **2020-06-14, 1399/03/25**

Update count: **0**

Registration date

2020-06-14, 1399/03/25

Registrant information

Name

Mohammad Javad Mahdizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3343 3099

Email address

mj.mahdizadeh@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of Visualization on Preoperative Anxiety in Patients Undergoing Endoscopic Urology Surgery

Public title

The Effect of Visualization on Anxiety in Urology patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients undergoing TURBT or TUL surgery Ability to communicate in Persian Age over 20 years Get a minimum score of 43 on the STAI scale in two sub-scales (State and Trait)

Exclusion criteria:

Patients who have been diagnosed with an specialist physician who has anxiety, depression or severe or emergency complications Anyone who refuses to continue companionship for any reason during the study will be excluded from the study and replaced by predetermined eligible individuals.

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, participants will be selected on the basis of hospital admission and inclusion criteria. Then random allocation will be done by block with four blocks so that every night, eligible people will be palced in intervention group based on computer-assinged block and as the intervention group will be identified every night, there will be a group intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this single-blind study, sampling will be done by people who are unaware of the nature of the groups and can also be randomly selected by someone who is unaware of the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kerman University of Medical Sciences

Street address

7 Bagh e Alavi/ Campus of Kerman University of Medical Sciences

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2020-06-01, 1399/03/12

Ethics committee reference number

IR.KMU.REC.1399.155

Health conditions studied**1****Description of health condition studied**

Bladder Tumor

ICD-10 code

C67

ICD-10 code description

Malignant neoplasm of bladder

2**Description of health condition studied**

Urolithiasis

ICD-10 code

N21

ICD-10 code description

Calculus of lower urinary tract

Primary outcomes**1****Description**

Anxiety score in Spielberger (STAI) questionnaire

Timepoint

Anxiety measurement at the beginning of the study (before the intervention)

Method of measurement

State-Trait Anxiety Inventory (STAI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention in this study is Visualization through visual and auditory animation. The researcher, after obtaining the appropriate animation about the type of surgery, will submit the file to the urologist for appropriate assessment of the type of surgery; Sound will be added to the images after the animation has been confirmed by the Urologist. The approximate time of animation and presentation is 15 minutes. Patients in the intervention group will be seen surgery animations as a group in conference room .

Category

Treatment - Other

2

Description

Control group: Patients in the control group will receive only routine surgical care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital

Full name of responsible person

Reza Mohammadi

Street address

Gharani Street

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76137-47181

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reza.m2034@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Mohammad Javad Mahdizadeh

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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

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