Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Abbas Pardakhty

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Campus of Kerman Uni of Med Sci, 7Bagh Alavi

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abpardakhty@kmu.ac.ir

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

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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