Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of virtual reality glasses on intra-operative stress and pain during intra-corporeal lithotripsy under spinal anesthesia

Protocol summary

Study aim

The aim of this study is to evaluate the effect of using virtual reality glasses on stress and pain during intra-corporeal lithotripsy under spinal anesthesia.

Design

in this RCT with a control group, without blinding, 90 patients are randomized to two groups.

Settings and conduct

The patients who were candidates for Transurethral lithotripsy because of nephrolithiasis in urether in urology ward, Imam Khomeini Hospital were randomized to two groups by block randomization method. patients in intervention group used a Virtual reality headset from 10 min before surgery till the end. Control group received no intervention. Stress level of patients was recorded before and after surgery by STAI questioner. also pain level (with VAS) before and after surgery, and Vital signs including Blood pressure, Heart rate, and the amount of sedatives were recorded by a single nurse practitioner.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18 to 65 years undergoing Trans Ureteral Lithotripsy surgery due to ureteral stones. Exclusion criteria: Patients requiring complete anesthesia; patients requiring emergency surgery; significant impairments of the senses of vision and hearing; history of epilepsy.

Intervention groups

Patients in the intervention group use virtual reality glasses from 10 minutes before surgery until the end of the procedure. There is no intervention in the control group during surgery.

Main outcome variables

Pain level, stress level, Vital signs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180331039164N1**
Registration date: **2019-02-05, 1397/11/16**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-05, 1397/11/16**
Update count: **0**

Registration date

2019-02-05, 1397/11/16

Registrant information

Name

Amir Mohammad Papan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2019-05-21, 1398/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of virtual reality glasses on intra-operative stress and pain during intra-corporeal lithotripsy under spinal anesthesia

Public title
Effect of virtual reality glasses on intra-operative pain during lithotripsy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
From 18 years old to 65 years old Candidate for Trans Ureteral Lithotripsy for ureteral stone
Exclusion criteria:
Patients who need complete anesthesia. Patients in need of emergency surgery Significant impairments of the senses of vision and hearing History of epilepsy People who suffer from headache, nausea and vomiting due to using the glasses.
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: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Assignment of patients in two groups of test and control will be done by Block Balanced Randomization (BBR) method. The Randomization Sequence will be generated with using the free website at http://www.randomization.com.
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 Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd
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Khouzestan
Postal code
15794-61357
Approval date
2018-03-06, 1396/12/15
Ethics committee reference number
IR.AJUMS.REC.1396.1064

Health conditions studied

1

Description of health condition studied
Calculus of ureter
ICD-10 code
N20.1
ICD-10 code description
Calculus of ureter

Primary outcomes

1

Description
The stress level of patients according to State-trait Anxiety Inventory
Timepoint
At the beginning of study (before the surgery) and after the end of surgery
Method of measurement
State-trait Anxiety Inventory

2

Description
pain acording to VAS scale
Timepoint
At the beginning of study (before the surgery) and after the end of surgery
Method of measurement
asking the patient acording to VAS scoring system

3

Description
patient's Blood Pressure before, every 10 minutes and after surgery
Timepoint
At the beginning of study (before the surgery) and after the end of surgery
Method of measurement
holter monitoring

4

Description
patient's pulse rate before, every 10 minutes and after surgery
Timepoint
continues before, during and after surgery
Method of measurement
continues ECG monitoring

Secondary outcomes

1

Description
Side effects
Timepoint
Every 20 minutes during the surgery and at the end of surgery
Method of measurement
Clinical observations

Intervention groups

1

Description
Intervention group: Patients in the intervention group use virtual reality glasses (Quilo brand) from the 10 minutes before surgery until the end of the procedure.
Category
Treatment - Devices

2

Description
Control group: There is no intervention in the control group during surgery.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Ahvaz 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
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Dinyar Khazaeli
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Assistant professor
Latest degree
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Student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

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