

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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

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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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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 according to VAS scale

Timepoint

At the beginning of study (before the surgery) and after the end of surgery

Method of measurement

asking the patient according 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

Dinyar Khazaeli

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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

Ahvaz University of Medical Sciences

Full name of responsible person

Dinyar Khazaeli

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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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