Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Assessing the Impact of Intra-operative Virtual Reality Immersion on Anesthetic Consumption, Anxiety, Pain and Patient Satisfaction in Anterior Cruciate Ligament Reconstruction: A Randomized Clinical Trial

Protocol summary

Study aim

Evaluating the effectiveness of immersive virtual reality as an intra-operative pain and anxiety management method in ACL reconstruction surgery

Design

A two-arm parallel group randomized clinical trial, non-blinded, phase 3, with a sample size of 25 patients in each group, utilizing a pool of opaque sealed envelopes for randomization.

Settings and conduct

The research will take place at Akhtar Hospital in Tehran. Patients assigned to the virtual reality group will be exposed to a tranquil virtual environment. They will receive comprehensive explanations regarding the procedure and reassurances that they have the option to halt the use of the virtual reality goggles at any point during the procedure if they experience any adverse effects like nausea, vomiting, or headaches. The experiment will utilize the Oculus Quest 2 virtual reality headset, displaying serene landscapes encompassing plains, forests, and seas, accompanied by calming music played for the patient in the operating room.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ACL reconstruction surgical operation indication, informed consent, age between 18 to 65 years. Exclusion conditions: Any uncontrolled systemic disease, history of seizures, history of migraines, inner or middle ear disorders

Intervention groups

Virtual Reality Group: Patients undergoing ACL reconstruction surgical procedures who are immersed in a calming virtual reality environment during surgery using a virtual reality device. Control Group: Patients undergoing ACL reconstruction surgical procedures in the usual manner without utilizing the virtual reality device

Main outcome variables

The amount of anesthetic drugs used during the surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230522058251N5**
Registration date: **2025-10-10, 1404/07/18**
Registration timing: **registered_while_recruiting**

Last update: **2025-10-10, 1404/07/18**
Update count: **0**

Registration date

2025-10-10, 1404/07/18

Registrant information

Name
Mohammad Hossein Mahrooz
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-06, 1404/06/15

Expected recruitment end date

2025-12-06, 1404/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessing the Impact of Intra-operative Virtual Reality Immersion on Anesthetic Consumption, Anxiety, Pain and Patient Satisfaction in Anterior Cruciate Ligament Reconstruction: A Randomized Clinical Trial

Public title
Exploring How Virtual Reality During ACL Surgery Affects Anesthesia Use, Anxiety, Pain, and Patient Satisfaction

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Indication for unilateral anterior cruciate ligament repair surgery Informed consent to participate in the clinical trial Age between 18 to 65 years

Exclusion criteria:
Uncontrolled systemic diseases History of seizure History of migraine History of inner ear or middle ear dysfunction

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was carried out using sequentially numbered, opaque, sealed envelopes prepared by an independent researcher not otherwise involved in the trial. The random allocation sequence was generated in advance using a table of random numbers and arranged in blocks of variable size to ensure balanced allocation between the study arms. Each envelope contained a single assignment slip indicating the intervention group. The envelopes were identical, tamper-proof, and stored in a secure location. At the time of enrollment, once eligibility was confirmed and informed consent obtained, each participant opened the next envelope in sequence to determine the allocation, which was then recorded by the recruiting investigator.

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
Research ethics committee of vice-chancellor in research affairs - Shahid Beheshti University of Med

Street address
7th Floor, Bldg No.2 SBMU, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2025-05-11, 1404/02/21

Ethics committee reference number
IR.SBMU.RETECH.REC.1404.123

Health conditions studied

1

Description of health condition studied
Acute ACL tear - right knee

ICD-10 code
S83.511A

ICD-10 code description
Sprain of anterior cruciate ligament of right knee, initial encounter

2

Description of health condition studied
Acute ACL tear - left knee

ICD-10 code
S83.512A

ICD-10 code description
Sprain of anterior cruciate ligament of left knee, initial encounter

Primary outcomes

1

Description
The amount of anesthetic drug administered to the patient

Timepoint
After entering the operation room and during the surgical procedure

Method of measurement
The amount of Midazolam or Fentanyl injected to the patient as recorded in the surgery report note

Secondary outcomes

1

Description
Pain

Timepoint
10 minutes after the patient is recovered in the post-anesthesia care unit (PACU)
Method of measurement
Visual Analogue Scale (VAS)

2

Description
Anxiety during surgery
Timepoint
10 minutes after the patient is recovered in the post-anesthesia care unit (PACU)
Method of measurement
Hospital Anxiety and Depression Scale (HADS)

3

Description
Patient satisfaction
Timepoint
10 minutes after the patient is recovered in the post-anesthesia care unit (PACU)
Method of measurement
Visual Analogue Scale (VAS)

Intervention groups

1

Description
Intervention Group: Patients undergoing ACL reconstruction surgery who receive fentanyl and midazolam as needed during the procedure, based on the anesthesiologist's judgment.
Category
Treatment - Devices

2

Description
Control group: Candidates for ACL reconstruction surgery who during the surgery, receive fentanyl and midazolam according to the standard protocol and under the supervision of the anesthesiologist
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhtar orthopedic hospital
Full name of responsible person
Seyed Morteza Kazemi
Street address
Akhtar hospital, Azar dead end,Sharifimanesh st, Shariati st, Tehran
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Email
akhtarhospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Morteza Kazemi
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Akhtar hospital, Azar dead end,Sharifimanesh st, Shariati st, Tehran
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Postal code
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Phone
+98 21 2200 1072
Email
akhtarhospital@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Hossein Mahrooz
Position
Medical Doctor
Latest degree
Medical doctor
Other areas of specialty/work

Orthopedics

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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
The data in this study include patients' age, sex, type of surgery, duration of the procedure, the type and amount of anesthetic drug administered, pain, anxiety, and patient satisfaction. All data will be anonymized to ensure patient confidentiality

When the data will become available and for how long
Data will be available as soon as the article is published

To whom data/document is available
Researchers in every university, or other scientific research institutes

Under which criteria data/document could be used
The data will be anonymized to ensure patient confidentiality

From where data/document is obtainable
To access data please contact the corresponding author using the contact information included in the published article

What processes are involved for a request to access data/document
The request should be formally submitted in a formal letterhead from the university or research institute as the requesting party for the corresponding author

Comments