Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The impact of immersion in virtual reality on the amount of anesthetic drugs used during upper limb surgeries

Protocol summary

Study aim
Evaluating the effectiveness of immersive virtual reality as an intra-operative pain management method

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 before undergoing the supraclavicular block. They will receive comprehensive explanations regarding the block 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. Additionally, the dosage of midazolam (0.01 mg/kg/dose) will be adjusted according to the patient's need. 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 both the block room and operating room.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Upper limb surgical operation indication, informed consent, age between 18 to 65 years. Exclusion conditions: Any uncontrolled systemic disease, history of seizures, history of migraines, inner ear disorders

Intervention groups
Virtual Reality Group: Patients undergoing upper limb surgical procedures who are immersed in a calming virtual reality environment during nerve block and surgery using a virtual reality device. Control Group: Patients undergoing upper limb surgical procedures in the usual manner for nerve block and surgery 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: **IRCT20230522058251N2**
Registration date: **2024-01-18, 1402/10/28**
Registration timing: **prospective**

Last update: **2024-01-18, 1402/10/28**
Update count: **0**

Registration date
2024-01-18, 1402/10/28

Registrant information

Name
Mohammad Hossein Mahrooz

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 912 130 8261

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mohamad.mahrooz@alum.sharif.edu

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-21, 1402/11/01

Expected recruitment end date
2024-02-19, 1402/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The impact of immersion in virtual reality on the amount of anesthetic drugs used during upper limb surgeries

Public title
Investigating the effect of immersion in virtual reality on the amount of anesthetic drugs used during upper limb surgeries

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Indication for upper limb 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 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
A pool of sealed, opaque envelopes containing a note with either of two phrases, 'Intervention Group' or 'Control Group,' is prepared in advance. Patients randomly chose one of these envelopes, and based on it, are allocated to either one of the two groups: intervention or control

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 Shahid Beheshti University of medical sciences
Street address
7th Floor, Bldg No.2 SBMU, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443

Approval date
2023-10-28, 1402/08/06

Ethics committee reference number
IR.SBMU.MSP.REC.1402.394

Health conditions studied

1

Description of health condition studied
Fracture of lower end of radius

ICD-10 code
S52.5

ICD-10 code description
Fracture of lower end of radius

2

Description of health condition studied
Carpal tunnel syndrome

ICD-10 code
G56.0

ICD-10 code description
Carpal tunnel syndrome

Primary outcomes

1

Description
The amount of anesthetic drug administered to the patient

Timepoint
before nerve block and during surgery

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

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Candidates for upper limb surgery who, before the start of supraclavicular block and during the operation, are placed under virtual reality immersion and receive fentanyl and midazolam at the discretion of the anesthesiologist

Category
Treatment - Devices

2

Description
Control group: Candidates for upper limb surgery who, during supraclavicular block and 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
بیمارستان ارتوپدی اختر

Full name of responsible person
Amir Bisadi

Street address
تهران - خیابان شریعتی - روبرو مترو قیطریه - خیابان شریفی منش - بن بست آذر- بیمارستان اختر

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1964714953

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Email
akhtarhospital@sbmu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Reza Minaei-Noshahr

Street address
Akhtar hospital, Azar dead end,Sharifimanesh st, Shariati st, Tehran

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Email
akhtarhospital@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Reza Minaei-Noshahr

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
Persons

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 Intern

Latest degree
Master

Other areas of specialty/work
Orthopedics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Amir Bisadi

Position
Assistant Professor of Orthopaedic hand suegery

Latest degree
Subspecialist

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Person responsible for updating data

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akhtarhospital@sbmu.ac.ir

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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The data in this study include patients' age, gender, type of surgery, duration of the procedure, and the type and amount of anesthetic drug administered. 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