

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of virtual reality application on pain associated with chest tube removal after cardiac surgery

Protocol summary

Study aim

Effect of virtual reality application on pain associated with chest tube removal after Coronary Artery Bypass Graft

Design

Clinical trials with intervention and control group, with parallel groups, randomized by binary blocks, 30 persons per group

Settings and conduct

The patients eligible for admission to the ICU and post ICU sections of Emam Reza and Ghaem Hospital. In the intervention group, the deviant techniques are implemented by the virtual reality headset. The list includes 5 video 360 degrees and the video is played through the virtual reality app 5 minutes before the chest tube is removed. At the end of the fifth minute, the nurse will remove the chest tube in a few seconds. In the control group, routine care is being performed. The pain intensity scale (VAS), before, immediately, and 15 minutes after tube withdrawal, and pain quality are measured by the modified McGill form before and 15 minutes later.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People aged 18-70 years undergoing open heart surgery; who have a mediastinal or pericardial chest tube; are now alert; are not attached to the ventilator; do not receive sedation; do not have severe vision or hearing problems; also They tend to cooperate in this study; Exclusion criteria: If the patient has unstable hemodynamic conditions, they will not be included in the study

Intervention groups

In the intervention group at the time of removal of the chest tube, the technique is performed by the virtual reality headset and performed in the routine care control group (mid-sit position, deep breath and chest tube withdrawal by nurse in a few secretions) and There is no other intervention

Main outcome variables

The severity and quality of pain resulting from the removal of the chest tube in patients undergoing coronary artery bypass graft surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190708044147N1**

Registration date: **2019-08-26, 1398/06/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-26, 1398/06/04**

Update count: **0**

Registration date

2019-08-26, 1398/06/04

Registrant information

Name

Fateme Seddighi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3609 1744

Email address

seddighif951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-01, 1398/05/10

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of virtual reality application on pain associated with chest tube removal after cardiac surgery

Public title
Effect of virtual reality application on pain associated with chest tube removal after cardiac surgery

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Have Iranian nationality Be Muslim Satisfied to participate in the study Age of more than 18 years and under 70 years Have enough eyesight with or without glasses Ability to speak Persian Minimum reading and writing literacy Awareness is sufficient to determine the severity and quality of the pain Heart disease (CABG) Have a pericardium or mediastinum tube Have not a companion disease that affects pain assessment (delirium, dementia, severe depression) Has not received an injectable soothing medicine from the previous 4 hours Do not have severe visual impairment and hearing loss Do not connect to the ventilator
Exclusion criteria:
 The patient does not have stable hemodynamic status

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The referred persons are assigned to the intervention and control groups by their entry into binary blocks. The allocation will be done by the PASS software

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 Mashhad University of Medical Sciences
Street address
 School of Nursing and Midwifery, Daneshgah Street, Ebne Sina Street
City
 Mashhad
Province
 Razavi Khorasan
Postal code
 9137913199
Approval date
 2019-05-28, 1398/03/07
Ethics committee reference number
 IR.MUMS.NURSE.REC.1398.027

Health conditions studied

1

Description of health condition studied
 pain associated with chest tube removal after cardiac surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
 Pain intensity score at the Visual Analogue Scale
Timepoint
 The severity of pain in the three stages (before, immediately and 15 minutes after the removal of the chest tube)
Method of measurement
 Visual Analogue Scale

2

Description
 Pain quality score in McGill questionnaire
Timepoint
 Before and 15 minutes after the chest tube exits
Method of measurement
 McGill questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
 Intervention group: In the intervention group, the

techniques are implemented by the virtual reality headset. First, a description of the method of intervention is given to the patient, then a list of 5 video 360 degrees with nature content and at least 5 minutes is provided to the patient to be selected to play a video. After selecting the video, the smartphone is placed inside the headset and the selected video is played back through the virtual reality app. From the 5 minutes before the breastbone is removed, the headset is placed on the patient and the video is played back. At the end of the fifth minute, the nurse steps out the chest tube according to the standard method, and after the video goes out, the video player stops and the glasses are removed from the patient's eyes.

Category

Rehabilitation

2

Description

Control group: Common care includes half-sitting position and deep breathing

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Tayyebi Mohammad

Street address

Imam Reza Hospital Square

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Phone

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Email

emamreza@mums.ac.ir

Web page address

<http://emamreza.mums.ac.ir/>

2

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Boostani Reza

Street address

Beginning at Ahmadabad Street, Dr. Ali Shariati Square

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Email

Quaem.Medical.Center@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Tafaghodi Mohsen

Street address

Mashhad University of Medical Sciences, Opposite Daneshgah Street 18, Daneshgah street

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dalir Zahra

Position

teacher

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Seddighi Fateme

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

No - There is not 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

Information on the main outcome measures of pain before and after the intervention, and side effects including pre- and post-intervention anxiety and stress, and pre-intervention fatigue, and information on the location of chest tube placement

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers in academic and scientific institutions

Under which criteria data/document could be used

In order to use the method of project implementation in other similar research and to cite the existing plan by researchers and students of academic institutions

From where data/document is obtainable

Central Library of Mashhad School of Nursing and Midwifery

What processes are involved for a request to access data/document

The data request will be sent to the responsible author's email and will be sent as soon as possible by the responsible author of the file.

Comments