

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Virtual Reality on Vital Signs, Oxygen Saturation of Arterial Blood and Pain of Patients During Outpatient Repair of the Skin Rupture in the Emergency Department of Shahid Beheshti Hospital in Qom

Protocol summary

Study aim

The effect of using virtual reality on vital signs and patients' pain perception during outpatient repair of skin rupture in the emergency department.

Design

In this clinical trial study, 80 patients will be selected by available sampling method and randomly assigned to the intervention (40 patients) and control (40 patients) groups using randomized block method. Data collection tools include a pain questionnaire and a vital signs checklist.

Settings and conduct

This study will be performed in the emergency department of Shahid Beheshti Hospital in Qom. No blinding will be performed in this study. In the control group, only lidocaine will be used to reduce patients' pain during repair of the skin rupture. In the intervention group, in addition to the usual care virtual reality glasses will be used and a video containing natural landscapes along with the sounds of nature will be played to the patients. Patients' vital signs and pain will be measured immediately before and immediately after the intervention.

Participants/Inclusion and exclusion criteria

Major inclusion criteria: age over 18 years; having rupture on the upper or lower limbs. Major exclusion criteria: the patient refuses to continue participating in the study; patients who need blood transfusions; patients who need tendon or artery repair; concomitant use of other anesthetic methods in addition to lidocaine.

Intervention groups

In the control group, only lidocaine will be used to reduce patients' pain during repair of the skin rupture. In the intervention group, in addition to the usual care, virtual reality glasses will be used and a video containing natural landscapes along with the sounds of nature will be played to the patients.

Main outcome variables

Stabilization of vital signs and reduction of patients' pain perception during outpatient repair of skin rupture.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150724023314N3**

Registration date: **2021-03-28, 1400/01/08**

Registration timing: **prospective**

Last update: **2021-03-28, 1400/01/08**

Update count: **0**

Registration date

2021-03-28, 1400/01/08

Registrant information

Name

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Name of organization / entity

Qom university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-30, 1400/01/10

Expected recruitment end date

2021-04-20, 1400/01/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Virtual Reality on Vital Signs, Oxygen Saturation of Arterial Blood and Pain of Patients During Outpatient Repair of the Skin Rupture in the Emergency Department of Shahid Beheshti Hospital in Qom

Public title
The Effect of Virtual Reality on Vital Signs, Oxygen Saturation of Arterial Blood and Pain of Patients During Outpatient Repair of the Skin Rupture

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Age over 18 years Having rupture on the upper or lower limbs No history of hearing or vision disorders
Exclusion criteria:
 The patient refuses to continue participating in the study Patients who need blood transfusions Patients who need tendon or artery repair Concomitant use of other anesthetic methods in addition to lidocaine

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be assigned to intervention and control groups using block randomized method. The link "https://www.sealedenvelope.com/simple-randomiser/v1/lists" will be used for block randomization. For this purpose, the target number of samples (200 samples including sample loss), number of groups (two groups A and B) and number of blocks (4) will be entered and the system will provide the researcher with a list of 4 blocks. Based on the output list, it will be determined in which group the patients who enter the study should be placed in order. Items A represent the intervention group and items B represent the control group.

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 Qom University of Medical Sciences

Street address

Qom University of Medical Sciences, Saheli street, Qom

City

Qom

Province

Ghoum

Postal code

3713649373

Approval date

2020-11-04, 1399/08/14

Ethics committee reference number

IR.MUQ.REC.1399.197

Health conditions studied

1

Description of health condition studied

Skin rupture

ICD-10 code

T81.33

ICD-10 code description

Disruption of traumatic injury wound repair

Primary outcomes

1

Description

Pain

Timepoint

Immediately before and immediately after repair of the skin rupture

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Blood pressure

Timepoint

Immediately before and immediately after repair of the skin rupture

Method of measurement

Vital Sign Monitoring Device

2

Description

Heart rate

Timepoint

Immediately before and immediately after repair of the skin rupture

Method of measurement

Vital Sign Monitoring Device

3

Description

Respiratory rate

Timepoint

Immediately before and immediately after repair of the skin rupture

Method of measurement

Vital Sign Monitoring Device

4

Description

Arterial blood oxygen saturation

Timepoint

Immediately before and immediately after repair of the skin rupture

Method of measurement

Vital Sign Monitoring Device

Intervention groups

1

Description

In the intervention group, during the repair of skin rupture, in addition to injecting 3-5 cc of 2% lidocaine ampoule subcutaneously, a film containing natural landscapes will be played to patients for 20 minutes. VRBOX branded virtual reality headsets will be used for video playback. The intervention will be done only once and during the repair of the skin rupture.

Category

Other

2

Description

In the control group, 3-5 cc of 2% lidocaine ampoule will be injected subcutaneously immediately before repairing the skin rupture to control the patient's pain.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital of Qom

Full name of responsible person

Mohammad Abbasinia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

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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

Ghoum 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

Ghoum University of Medical Sciences

Full name of responsible person

Mohammad Abbasinia

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable