

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Influence of Virtual Reality on catheterization pain control in 6-12 years old patients

Protocol summary

Summary

This study aims to provide a drug-free, easy and effective way to control the pain caused by catheterization in children. Inclusion criteria: children aged 12-6 years candidate for getting catheter. Exclusion criteria: history of hospitalization and IV received analgesics before catheterization, refractive vision problems (astigmatism, lens and glasses ...), and the experience of virtual space, agitated, critically ill and toxic children with special status, and unconsciousness. Totally, 126 children will participate in both the intervention and control groups. After collecting the samples, the informed consent form will be obtained from the child's guardian. Two minutes before venipuncture, virtual space is used to familiarize children and this process continues until end. The time of venipuncture will be calculated from arrival of needle to IV fixation. 10 minutes after the process, we would ask participants to explain their pain experience during venipuncture using the Oucher and select a picture shows the amount of pain. In the control group, all of the steps will be implemented except the virtual space.

General information

Acronym

Virtual Reality - VR

IRCT registration information

IRCT registration number: **IRCT201211204490N2**

Registration date: **2012-12-17, 1391/09/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-17, 1391/09/27

Registrant information

Name

Mohadese Babaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 5366

Email address

hadisbabaie@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Qazvin University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Influence of Virtual Reality on catheterization pain control in 6-12 years old patients

Public title

catheterization pain control

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Iranian children aged 12-6 years candidate for getting catheter. Exclusion criteria: history of hospitalization and IV received analgesics before catheterization; refractive vision problems (astigmatism, lens and glasses ...); the experience of virtual space; agitated, critically ill and toxic children with special

status, and unconsciousness.

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research, Qazvin University of
Medical Sciences

Street address

Shahid Bahonar boulevard

City

Qazvin

Postal code

Approval date

2012-10-29, 1391/08/08

Ethics committee reference number

28/20/6507

Health conditions studied

1

Description of health condition studied

control the pain caused by catheterization

ICD-10 code

Z51.9

ICD-10 code description

Medical care, unspecified

Primary outcomes

1

Description

pain caused by catheterization

Timepoint

10 minutes after the catheterization

Method of measurement

Oucher scale (Faces Pain Scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: Two minutes before venipuncture, virtual
space is used to familiarize children and this process
continues until end.

Category

Prevention

2

Description

Control: no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods hospital in Qazvin

Full name of responsible person

Street address

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Qazvin University of
Medical Sciences

Full name of responsible person

Dr. Saeid Asefzade

Street address

Shahid Bahonar boulevard

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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

Vice chancellor for research, Qazvin University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Nursing and Midwifery department, Qzvin University
of Medical Sciences

Full name of responsible person

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty