

# 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

##### City

Qazvin

#### 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**

Mohadese Babaie

**Position**

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Nursing and Midwifery department, Qzvin University  
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**Full name of responsible person**

Mehdi Hosseini

**Position**

Nurse

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

Mehdi Hosseini

**Position****Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email**

mehos2007@yahoo.com

**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*