

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Comparison the effect of Distraction on two methods of virtual reality and guided visualization on pain caused by venous cannulation in hemodialysis patients

#### Protocol summary

##### Study aim

Determining the Effect of Virtual Reality and Guided Imaging Technique on the Pain Caused by the Injection of Catheter in Hemodialysis Patients

##### Design

The clinical trial includes a group that initially receives intervention 1 (guided visualization technique) and then intervention 2 (virtual reality). The sample size is 60 people without randomization. The trial phase does not apply to this study.

##### Settings and conduct

This study will be carried out at Bhlul Hospital in Gonabad. The diversion of thought is guided by the technique of visualization and virtual reality technology, and its effect on the pain caused by cannulation will be measured.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age of 18-60; Awareness of time, place and persons at the time of data collection; Minimal reading and writing skills  
No entry Criteria: Lack of Diabetic neuropathy; history of mental illness; continues use of analgesics 24 hours before hemodialysis; damaged skin in the intended position; ; use of alcohol and drugs

##### Intervention groups

Intervention 1: Distraction with the guided visualization technique in two intermittent dialysis sessions  
Intervention 2: Deviation of thought with virtual reality technology in two intermittent dialysis sessions

##### Main outcome variables

Pain intensity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171219037966N3**

Registration date: **2018-06-13, 1397/03/23**

Registration timing: **retrospective**

Last update: **2018-09-06, 1397/06/15**

Update count: **2**

##### Registration date

2018-06-13, 1397/03/23

##### Registrant information

###### Name

Amirreza Nasirzadeh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 5722 3028

###### Email address

nasirzadeh@gmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-13, 1396/12/22

##### Expected recruitment end date

2018-06-10, 1397/03/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of Distraction on two methods of virtual reality and guided visualization on pain caused by venous cannulation in hemodialysis patients

**Public title**

Comparison of the effect of two virtual reality methods and guided visualization on intravenous cannulation pain

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age of 18 to 60 years Awareness of time, place and persons at the time of data collection Minimal the reading and writing skills

**Exclusion criteria:**

history of mental illness diabetic neuropathy patient unwillingness to continue the study continues use of analgesics 24 hours before hemodialysis use of alcohol and drugs damaged skin in the intended position

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Crossover

**Other design features**

Due to intervention and outcome evaluation, the researcher, investigator and analyst assistant does not know the type of intervention performed during the sessions.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Gonabad University of Medical Sciences

**Street address**

Asian Roadside Border

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

9691793718

**Approval date**

2018-03-12, 1396/12/21

**Ethics committee reference number**

IR.GMU.REC.1396.163

**Health conditions studied****1****Description of health condition studied**

chronic renal failure

**ICD-10 code**

N18.5

**ICD-10 code description**

Chronic kidney disease, stage 5

**Primary outcomes****1****Description**

pain

**Timepoint**

The beginning of the study; the first intervention session and 2, 9 and 11 days after the first intervention

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group number 1: After receiving informed consent from the patient, the demographic questionnaire is filled in half an hour before the intervention. Then, 25 minutes before hemodialysis, the patients are in supine position, then a few deep abdominal cavities and a diaphragm with closed eyes and comfortable in the best condition in which it relaxes. By providing a quiet, quiet environment and by minimizing environmental stimuli (such as low-light room, walking limits) into an audio file and focusing on the visualization of an illustration, a desirable scenario of listening to the stage-by-stage relaxation of the limbs will be listened without any muscle movement. Audio file The content of mental imagery is played back for 20 minutes, taking into account the sound level between 21 and 10 dB (calibrated by the audiometric expert) so that the person who narrates the text's speaker in the visualization state of the image is in the desired desirable landscape. Then the data will be collected by the researcher's assistant when the file passes for 15 minutes (5 minutes to complete the audio). During cannulation, the patient determines the intensity of his pain by marking a 10-cm line. The assistant researcher measures and records the distance between the zero point and the location of the sign.

**Category**

Other

## 2

### Description

Intervention group number 2: In the virtual reality group, 10 minutes before the dialysis, special glasses are placed on the head of the patient and they spend 20 minutes spelling pictures designed to reduce pain. After 15 minutes of playing the file, during the watch, the fistula placement and the pain score will be measured by the researcher's assistant. During cannulation, the patient determines the intensity of his pain by marking a 10-cm line. The assistant researcher measures and records the distance between the zero point and the location of the sign.

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Bohloul Hospital

##### Full name of responsible person

Amir Rafie

##### Street address

Asian Road

##### City

Gonabad

##### Province

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##### Postal code

9691793718

##### Phone

+98 51 5722 3028

##### Email

a.rafie2000@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Imam Reza hospital

##### Full name of responsible person

Amirreza Nasirzadeh

##### Street address

Imam Reza hospital, The margin of Imam Reza Square (AS), Ibn Sina St, Mashhad, Iran.

##### City

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##### Province

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##### Phone

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##### Email

nasirzadeharnz@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Gonabad University of Medical Sciences

##### Full name of responsible person

Dr. Seyed Ali Sajjadi

##### Street address

Gonabad University of Medical Sciences, Asian Roads, Gonabad, Khorasan Razavi, Iran

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##### Province

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##### Phone

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##### Email

moallef@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Gonabad University of Medical Sciences

#### Proportion provided by this source

30

#### 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

Gonabad University of Medical Sciences

##### Full name of responsible person

Amirreza Nasirzadeh

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

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## Person responsible for scientific inquiries

**Contact**

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Gonabad University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Habib Shareinia

**Position**

MSc

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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shareinia.msn@gmail.com

## 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**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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