

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

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Email address

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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

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2

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Amirreza Nasirzadeh

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

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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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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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Contact

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Position

Assistant Professor

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Specialist

Other areas of specialty/work

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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

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