

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Various Mirror Reflection Visual Illusion on Pain Intensity due to Needle Insertion in Arterio-Venous Fistula Hemodialysis Patient's

Protocol summary

Study aim

Determination of the effect of reflection of mirrors (flat and convex) with and without adjustment phase on severity of pain due to needle insertion into the arterial fistula of the hemodialysis patients

Design

A Clinical trial with one group (before and after)

Settings and conduct

The study will be done in the hemodialysis unit of Mashhad montaseriye and Hefdah Shahrivar Hospital. 30 hemodialysis patients whose vascular access is through arterial venous fistula are selected according to the inclusion criteria by simple random sampling method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hemodialysis sessions three times a week; vascular access of arterial venous fistula; to be under hemodialysis through the current fistula for at least 6 months; age range of 18-70; awareness of time, place and person; ability to speak and understand Persian
Exclusion criteria: fever of more than 37.5 degrees; oral or local intake of painkiller or sedation less than 6 hours before hemodialysis; use of psychoactive drugs 24 hours before hemodialysis; skin disorders at the injection site (ulcer, sensitivity, redness, secretion); problems with vision and myopia disturbances (30 cm or less)

Intervention groups

Each patient will be studied during 5 sessions. In the first session, as the control session, there is no intervention. During the next four sessions, one of two types of mirrors (flat and convex) will be used. Each mirror is used in 2 sessions.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180412039277N1**

Registration date: **2018-06-07, 1397/03/17**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-31, 1397/10/10**

Update count: **1**

Registration date

2018-06-07, 1397/03/17

Registrant information

Name

Zahra Rajabzadeh Malayjerdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3623 7295

Email address

rajabzadehmz1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-28, 1397/02/08

Expected recruitment end date

2018-06-19, 1397/03/29

Actual recruitment start date

2018-06-05, 1397/03/15

Actual recruitment end date

2018-08-14, 1397/05/23

Trial completion date

2018-08-14, 1397/05/23

Scientific title

The Effect of Various Mirror Reflection Visual Illusion on Pain Intensity due to Needle Insertion in Arterio-Venous Fistula Hemodialysis Patient's

Public title

The Effect of Mirror Reflection Visual Illusion on Pain

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having informed Consent to Participate in all Study Sessions Hemodialysis Sessions should be three times a Week Vascular Access to the Arterial Venous Fistula Passing at least 6 Months from Hemodialysis via current Fistula Being able to Speak and Understand Persian Orientation to time, place and person

Exclusion criteria:

Visual Impairment and Disturbed Close Vision (30 cm or less) Skin Disorders at the Injection Site (Wound, Sensitivity, Redness, Secretion) using oral, topical or sedative drugs during 6 hours before Hemodialysis using Psychoactive Drugs 24 hours before Hemodialysis Fever Greater than 37.5 Celsius Degrees

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Actual sample size reached: **30**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Quraishi Building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2018-04-07, 1397/01/18

Ethics committee reference number

IR.MUMS.REC.1397,9

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

The pain caused by the insertion of fistula needles in hemodialysis patients

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain intensity

Timepoint

During the 5 sessions of hemodialysis (control and intervention sessions) immediately after the needle is inserted into the fistula

Method of measurement

Pain Visual Analogue Scale

Secondary outcomes**1****Description**

The amount of visual illusion

Timepoint

During the 4 sessions of hemodialysis (intervention sessions), immediately after the needle is inserted into the fistula

Method of measurement

Longo Questionnaire

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

Control session (first sampling session): Needle entry to the fistula is performed by the nurse of the hemodialysis unit without any intervention. Intervention sessions (second and third sampling sessions): The hospital bed's nightstand will be placed in front of the patient. We ask the patient to put his both hands on the table. The mirror of that session, which has been randomly selected for that session in advance, will be placed between the patient's hands at a distance of 30 cm from the forefinger of each hand, so that the healthy hand will be in front of the mirror and the hand with the fistula will be behind the mirror. We ask the patient to look at the picture of his healthy hand in the mirror. Immediately, the needle is inserted into the fistula of the hand behind the mirror by the nurse of the hemodialysis unit.

Intervention sessions (fourth and fifth sampling sessions): The hospital bed's nightstand will be placed in front of the patient. We ask the patient to put both hands on the table. The mirror of that session, which has been randomly selected for that session in advance, is placed between the patient's hands at a distance of 30 cm from the forefinger of each hand, so that the healthy hand is in front of the mirror and the hand with the fistula is behind the mirror. We ask the patient to look at the picture of his healthy hand in the mirror for ten minutes. After ten minutes, the needle is inserted into the fistula of the hand behind the mirror by the nurse of the hemodialysis unit.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
17 Shahrivar hospital
Full name of responsible person
Javad Malekzadeh
Street address
Koohsangi Street
City
Mashhad
Province
Razavi Khorasan
Postal code
1111111111
Phone
+98 51 3343 2335
Email
Malekzadehj@mums.ac.ir

2

Recruitment center

Name of recruitment center
montaserieh hospital
Full name of responsible person
Javad Malekzadeh
Street address
janat
City
mashhad
Province
Razavi Khorasan
Postal code
1111111111
Phone
+98 51 3343 2335
Email
Malekzadehj@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Quraishi Building, Daneshgah Street
City
Mashad
Province
Razavi Khorasan
Postal code
9919191778
Phone
+98 51 3841 3007
Email
presidentoffice@mums.ac.ir
Web page address
<http://v-research.mums.ac.ir/>

Grant name

Grant code / Reference number

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

Title of funding source

Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Zahra Rajabzadeh Malayjerdi
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Faculty of Nursing and Midwifery, Ebne Sina Street,
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511

Fax
+98 51 3859 7313
Email
rajabzadehmz1@mums.ac.ir
Web page address
<http://nurse.mums.ac.ir/index.php>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Zahra Rajabzadeh Malayjerdi
Position
Masters Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Faculty of Nursing and Midwifery, Ebne Sina Street,
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Fax
+98 51 3859 7313
Email
rajabzadehmz1@mums.ac.ir
Web page address
<http://nurse.mums.ac.ir/index.php>

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Zahra Rajabzadeh Malayjerdi
Position
masters student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Faculty of Nursing and Midwifery, Ebne Sina Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
rajabzadehmz1@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

I do not want to explain more

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available