

# 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**  
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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  
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## 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**  
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**Province**  
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**Phone**  
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**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  
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## Person responsible for scientific inquiries

### Contact

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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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masters student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
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## 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