

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Comparison of the effect of guided visualization technique and cryotherapy on the pain intensity of needle insertion into arterial-venous vessels of hemodialysis patients: a clinical trial

#### Protocol summary

##### Study aim

Reducing pain and improving the quality of life of hemodialysis patients A cheap and effective method that replaces the usual expensive methods Improving the quality of nursing care Reducing the costs of the patient and the health

##### Design

Randomized crossover clinical trial with control group, no blind strain, randomized, phase 2 on 60 patients, for randomization using Randomization main software, a random sequence table was created.

##### Settings and conduct

Hemodialysis Department of Dr. Ali Shariati Hospital, Fasa. This study was conducted in 3 stages, in each stage, each group received guided visualization technique, cryotherapy and control separately.

##### Participants/Inclusion and exclusion criteria

People over 18 years old, aware of the time, place and person, not having eczema and wounds at the massage site, having a fistula and at least 6 weeks of dialysis history. Exclusion criteria are having mental illness and peripheral vascular disease, history of using painkillers and similar compounds 8 hours before dialysis

##### Intervention groups

In guided visualization, the patient is asked to lie down on the bed, release his body and mind from tension, close his eyes, and then listen to the guided visualization CD, which includes the visualization of the forest, beautiful scenery, and positive affirmations, through headphones. It will be played for 18 minutes. In cryotherapy, the Hugo point, which is located on the back of the hand between the thumb and the forefinger, is rubbed with a 2x2 cube of ice wrapped in gauze and nylon for 10 minutes (2 minutes of rubbing and 15 seconds of rest). In the control group, the routine procedures of the dialysis department are performed.

##### Main outcome variables

Reducing pain and improving the quality of life of hemodialysis patients A cheap and effective way to control pain Reducing the costs of the patient and the health care system

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230808059078N1**

Registration date: **2023-08-21, 1402/05/30**

Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**

Update count: **0**

##### Registration date

2023-08-21, 1402/05/30

##### Registrant information

##### Name

Zahra Ghazanfari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5334 1349

##### Email address

zgh3038@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-07, 1402/06/16

##### Expected recruitment end date

2024-03-06, 1402/12/16

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of guided visualization technique and cryotherapy on the pain intensity of needle insertion into arterial-venous vessels of hemodialysis patients: a clinical trial

**Public title**  
Comparison of the effect of guided visualization technique and cryotherapy on the pain intensity of needle insertion into arterial-venous vessels of hemodialysis patients: a crossover clinical trial

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Having a fistula and at least 6 weeks history of dialysis  
No eczema and sores in the massage area  
Absence of disturbance in the level of consciousness  
Absence of peripheral vascular disease and neuropathy  
**Exclusion criteria:**  
Use of painkillers 8 hours before hemodialysis  
Having mental disorders recorded in the patient's file. No need to continue hemodialysis

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In order to allocate the sample people to the three study groups in the main randomization table, a random sequence was generated with 6 blocks of 10, and then to allocate each intervention to one person, a nursing expert who was outside the study group allocated the groups in the order of patients entering the study.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hormozgan University of Medical Sciences

##### Street address

Plate 48, Alley 9, Palestine Street

##### City

Fasa

##### Province

Fars

##### Postal code

7461793963

#### Approval date

2022-10-09, 1401/07/17

#### Ethics committee reference number

IR.HUMS.REC.1401.206

## Health conditions studied

### 1

#### Description of health condition studied

cryotherapy technique, guided visualization technique

#### ICD-10 code

#### ICD-10 code description

Preparatory care for dialysis

## Primary outcomes

### 1

#### Description

The percentage of people whose pain score is less than 10 after the guided visualization technique. The percentage of people whose pain score is less than 10 after the cryotherapy technique.

#### Timepoint

Measuring the amount of pain at the end of three techniques (guided visualization, cryotherapy and control) in three independent groups of 20 people during three stages with an interval of three days

#### Method of measurement

Numeric rating scale

## Secondary outcomes

### 1

#### Description

Pain control with a numerical measure of pain

#### Timepoint

Measuring the amount of pain at the end of three techniques (guided visualization, cryotherapy and control) in three independent groups of 20 people during three stages with an interval of three days

#### Method of measurement

Numeric rating scale

## Intervention groups

### 1

#### Description

The first intervention group: guided visualization technique. In guided visualization, a CD is played through headphones for 18 minutes, which includes the visualization of the forest, the sea, beautiful scenery and positive emphasis on reducing pain and increasing health.

#### Category

Treatment - Other

### 2

#### Description

The second intervention group: cryotherapy technique. In cryotherapy, a 2x2 ice cube was used to massage Hugo's point in the hand without fistula for 10 minutes (2 minutes of rubbing and 15 seconds of rest) before entering the needle.

#### Category

Treatment - Other

### 3

#### Description

Control group: received the routine procedures of the dialysis department.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hemodialysis Department of Dr. Ali Shariati Hospital,  
Fasa

##### Full name of responsible person

Arif Faqih

##### Street address

Plate 48, Alley 9, Palestine Street

##### City

Fasa

##### Province

Fars

##### Postal code

7461793963

##### Phone

+98 71 5334 1349

##### Email

zgh3038@gmail.com

##### Web page address

<http://irct.ir/fa/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bandare-abbas University of Medical Sciences

##### Full name of responsible person

Arif Faqih

##### Street address

Plate 48, Alley 9, Palestine Street

##### City

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##### Province

Fars

##### Postal code

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##### Phone

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##### Email

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##### Web page address

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#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Bandar Abbas University of Medical Sciences

#### Proportion provided by this source

1

#### 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

Bandare-abbas University of Medical Sciences

##### Full name of responsible person

Arif Faqih

##### Position

Faculty member of nursing department

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

##### Street address

Plate 48, Alley 9, Palestine Street

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##### Province

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##### Postal code

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##### Phone

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**Email**

zgh3038@gmail.com

**Web page address**

http://irct.ir/fa/

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Fasa University of Medical Sciences

**Full name of responsible person**

Zahra Ghazanfari

**Position**

Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data****Contact****Name of organization / entity**

Fasa University of Medical Sciences

**Full name of responsible person**

Zahra Ghazanfari

**Position**

Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Comparison of the effect of guided visualization technique and cryotherapy on the pain intensity of needle insertion into arterial-venous vessels of hemodialysis patients referring to the dialysis department of Shariati Hospital, Fasa city in 1401-1402: A crossover clinical trial

**When the data will become available and for how long**

The access period starts 8 months after the results are published

**To whom data/document is available**

For researchers working in academic, scientific and clinical institutions

**Under which criteria data/document could be used**

Data can be used for adults 18 years and older.

**From where data/document is obtainable**

Zahra Ghazanfari zgh3038@gmail.com

**What processes are involved for a request to access data/document**

8 months after the publication of the article, you can access the data of this article by sending a message to my email.

**Comments**