Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Fasa

Province
Fars

Postal code
7461793963

Phone
+98 71 5334 1349

Email
zgh3038@gmail.com

Web page address
http://irct.ir/fa/

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
Fars

Postal code
7461793963

Phone
+98 71 5334 1349

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
Street address
Plate 48, Alley 9, Palestine Street
City
Fasa
Province
Fars
Postal code
7461793963
Phone
+98 71 5334 1349
Email
zgh3038@gmail.com

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
Nursery
Street address
Plate 48, Alley 9, Palestine Street
City
Fasa
Province
Fars
Postal code
7461793963
Phone
+98 71 5334 1349
Email
zgh3038@gmail.com

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