Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 2026

Comparing the Effect of Cryotherapy on Hugo point and the Pain of Vascular Needles Insertion in Hemodialysis Patient

Protocol summary

Study aim
The unpleasant and stressful experiences of patients should be minimized.

Design
Clinical trial with two intervention groups, with parallel groups, without strain, simple randomization, table of random numbers, on 56 patients.

Settings and conduct
This study is carried out in Hami Arak Dialysis Center.Group A patients are placed in the venipuncture site under the intervention of using an ice pack. The ice bag is placed for 10 minutes on the place where the vascular needles are inserted and is moved clockwise with moderate pressure. After ten minutes, the ice pack is remove, after which cannulation is performed, and then pain intensity is measured with the VAS instrument within 1 minute at most after cannulation. Group B patients are placed at Hugo's point under the intervention of using an ice bag. In this method, the ice bag is moved clockwise for 10 minutes on the Hugo point, between the thumb and forefinger, on the back of the hand opposite to the cannulation, with moderate pressure. After ten minutes, the cannulation is done and then within 1 minute after the cannulation, the pain level is measured with the VAS tool.

Participants/Inclusion and exclusion criteria
Patient age, between 18-70 years. Having a fistula, at least 3 months. The patient should undergo hemodialysis 3 times a week. Regular hemodialysis

Intervention groups
Using an ice pack at the two places where the needle is inserted and Hugo's point, in order to compare the reduction of pain in these two points

Main outcome variables
The treatment team can reduce the pain and suffering of patients by using a local and easy method and increase the quality of nursing services; Raising the awareness of nurses about the benefits of using local pain relief methods and paying more attention to this issue.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220612055152N1**
Registration date: **2022-09-10, 1401/06/19**
Registration timing: **retrospective**

Last update: **2022-09-10, 1401/06/19**
Update count: **0**

Registration date
2022-09-10, 1401/06/19

Registrant information

Name
Atefeh Sasani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3222 9403

Email address
atefeh.sasani82@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-06, 1401/05/15

Expected recruitment end date
2022-08-18, 1401/05/27

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the Effect of Cryotherapy on Hugo point and the Pain of Vascular Needles Insertion in Hemodialysis Patient

Public title

"effect of cold therapy on pain"؛ "effect of Hugo point cold therapy on pain"

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness of the patient to participate in the study and have informed consent The patient's age should be between 18-70 years. The patient should have consciousness, verbal ability and normal sensation. Cannulation is not an emergency. The patient should not have any other pain in the hands except the pain caused by the cannulation. Lack of anesthesia and neuropathy disorders and peripheral vascular diseases at the cannulation site Do not have a history of mental illness. The patient has not used painkillers, anesthetics or drugs in the last 8 hours. Do not have skin problems such as eczema, burns, wounds or skin cuts at the cannulation site. Having a fistula, at least 3 months. The patient should undergo hemodialysis 3 times a week. Regular hemodialysis

Exclusion criteria:

The patient's unwillingness to cooperate with the study Allergy to cold Improper cannulation angle or more than one cannulation attempt

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: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is simple. The randomization unit is individual. The randomization tool is the table of random numbers. We number the statistical community from 1 to the last... and record each of the numbers on similar and identical small cards. Then we put all the cards in a box and every time after shaking the box, we randomly take out one card from the box and record its number. We continue this process until the desired number of sample units is obtained.

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

Arak University of Medical Sciences

Street address

22 Bahman St., Postal code 3813747773

City

Arak

Province

Markazi

Postal code

3813747773

Approval date

2022-03-07, 1400/12/16

Ethics committee reference number

IR.ARAKMU.REC.1400.329

Health conditions studied

1

Description of health condition studied

cold therapy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score in Visual Analogue Scale tool

Timepoint

Within 1 minute after cannulation, the pain level is measured with the Visual Analogue Scale tool.

Method of measurement

Visual Analogue Scale tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients are divided into two intervention groups, first and second. The cooler used in this research is made by YAKHPACK company of Iran. Its dimensions are 10 x 10 cm and its weight is approximately 100 grams, which is made of gelatinous and non-toxic materials. The alcohol pad used is from Saba Tab Company. The patients of the first intervention group are placed in the venipuncture site under the

intervention of using an ice pack. In this method, the needle entry point is marked before placing the ice pack. Then The ice pack is placed for 10 minutes on the place where the vascular needles are inserted and moved clockwise with medium pressure. (During 10 minutes: 15 seconds of rest for every 2 minutes). After ten minutes, the ice pack is removed and the area is sterilized with an alcohol pad, after which cannulation is performed, and then pain intensity is measured with a Visual Analogue Scale tool within 1 minute after cannulation.

Category

Prevention

2

Description

Intervention group: The patients of the second intervention group are placed in Hugo's point under the intervention of using an ice pack. In this method, the ice pack is moved for 10 minutes on the Hugo point, between the thumb and forefinger, on the back of the hand opposite to the cannulation, with moderate pressure, in a clockwise direction. (During 10 minutes: 15 seconds of rest for every 2 minutes). After ten minutes, the cannulation is done and then within 1 minute after the cannulation, the pain level is measured with the Visual Analogue Scale tool.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hami Arak Dialysis Center

Full name of responsible person

Ali Nowrozi

Street address

Shahrak Gerdo, Saadi St., Razi St

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3477 9080

Email

arak@hamidc.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Alireza Kamali

Street address

Sardasht, Basij Square, University Complex of the Prophet (PBUH)

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3524

Fax

+98 86 3417 3524

Email

nursing.school@arakmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Atefeh Sasani

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

22 Bahman St., Postal code 3813747773

City

Arak

Province

Markazi

Postal code

3813747773

Phone

+98 86 3222 9403

Email

atefeh.sasani82@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Atefeh Sasani

Position
Nurse

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
22 Bahman St., Postal code 3813747773

City
Arak

Province
Markazi

Postal code
3813747773

Phone
+98 86 3222 9403

Email
atefeh.sasani82@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Atefeh Sasani

Position
Nurse

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
22 Bahman St., Postal code 3813747773

City
Arak

Province
Markazi

Postal code
3813747773

Phone
+98 86 3222 9403

Email
atefeh.sasani82@gmail.com

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
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
Undecided - It is not yet known if there will be 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