

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison between two methods of non-pharmacological care on pain from entrance of needles in arteriovenous fistulas of hemodialysis patients

Protocol summary

Summary

Objective: Comparison between two methods of non-pharmacological care on pain from entrance of needle into AV fistula in hemodialysis patients. Design: single blind. Studied population: Patients under therapy with hemodialysis by AV fistula that has criteria to be studied. Sample size: Thirty five peoples. Studied intervention: Pain assessment will be performed during 12 consecutive dialysis sessions, 3 times in a week. The first three sessions will be done before intervention and next nine sessions will be conducted with three different interventions among all patients in identical sequence. Before the intervention: visual analogue scale of pain intensity will be measured, after entrance needle into fistula, in the first three dialysis sessions. Then in the second three dialysis sessions, false point in a wrist which does not have fistula will be massaged for 5 minutes before and during the entrance of the needle into the fistula. In the third three dialysis sessions the handing hoku point which does not have fistula, will be massaged for 5 minutes. In a dialysis session rhythmic breathing will be taught the patients as they could do that. Then in the fourth three sessions, patients will do this method for 5 minutes before and during the entrance of the needle into the fistula. Pain intensity will be measured by the VAS after each intervention and entrance of needle into fistula. The primary outcome: If it will be cleared the positive effects of interventions on pain intensity caused by the entrance of needles into VA fistula which is compared and measured by using pain visual criterion, it is recommended a method to reduce the pain with the acceptance of responsibility by patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013010111975N1**

Registration date: **2013-02-24, 1391/12/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-24, 1391/12/06

Registrant information

Name

Sophia Akbari

Name of organization / entity

Nursing and Midwifery School, Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vic Chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between two methods of non-pharmacological care on pain from entrance of needles in arteriovenous fistulas of hemodialysis patients

Public title

Non-pharmacological care of pain from needles in hemodialysis fistulas

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1-Patients with end-stage renal disease who are diagnosed by a doctor and they must be under therapy with hemodialysis at least three months before participating in this study; 2- Having arteriovenous fistula; 3-Be able to communicate verbally and visually; 4- Lack of vascular access problem; 5-Absence of neuropathic disorders; 6-Absence of peripheral vascular disease. Exclusion criteria: 1-Require more than one attempt to puncture the fistula; 2-Decrease level of consciousness and agitation; 3-Existence of Inflammation and bites or fracture on massaged point; 4-The use of other methods for reducing pain.

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: **35**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan university of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamedan

Postal code

Approval date

2013-01-01, 1391/10/12

Ethics committee reference number

3497/9/35/16/د/پ

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

R52.9

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

Pain

Timepoint

Before intervention and after each intervention.

Method of measurement

VAS (visual analogue scale).

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention: Pressure on the false point. At three dialysis sessions, researcher will massage false point for 5 minutes in a wrist which is lack of fistula, before and during the entrance of the needle into the fistula. Then after the entrance of the needle into the fistula, the pain intensity will be measured by VAS.

Category

Placebo

2

Description

The second intervention: At three dialysis sessions the handing hoku point will be massaged for 5 minutes before and during the entrance of the needle into fistula. Then pain intensity will be measured by VAS.

Category

Other

3

Description

The third intervention: At one dialysis session, rhythmic breathing will be taught.

Category

Behavior

4

Description

The fourth intervention: Patients before and during the entrance of needle into fistula will do rhythmic breathing for 5 minutes. Then pain intensity will be measured by VAS.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Sophia Akbari- MSC Student of Medical-Surgical Nursing

Street address

Besat Hospital, Shahid Motahari Ave. Hamedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vic Chancellor of Research and Technology, Hamadan University of Medical Sciences

Full name of responsible person

Dr Heidar Tavilani

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vic Chancellor of Research and Technology, Hamadan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Nursing and Midwifery School, Hamadan University of Medical Sciences

Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty