# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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

**Country**

Iran (Islamic Republic of)

**Phone**

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**Email address**

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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/پ/د

## 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
**City**
Hamedan

## 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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Hamedan
**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**
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## Person responsible for scientific inquiries

**Contact**
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Department of Internal Medicine and Surgery, Nursing and Midwifery School, Hamadan University of Med
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## Person responsible for updating data

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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*