

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparing the effect of cold and heat stimulation of the Hoku point on pain of needling arteriovenous fistulas in elderly patients undergoing hemodialysis

Protocol summary

Summary

The objective of this study is comparing the effect of cold and heat massage of the Hoku point on pain of needling arteriovenous fistula in elderly patients undergoing hemodialysis. This study is a randomized, single-blind clinical trial conducted in Akhavan hemodialysis center in Kashan, Iran, in 2014. The study was conducted on 24 elderly patients being in ages of 60 years and over who were chosen easily. Data collection was Performed using a two-party instrument. The first part consists of questions on demographic characteristics including age, gender, marital status,... The second part of the instrument was a visual analog scale (VAS) for assessing the severity of pain the patients experienced during needling the AVF; and this scale was recorded by a nurse who wasn't aware of the type of intervention. The intervention was performed by a researcher or an assistant researcher. To remove the effect of inculcation on patients, interventions were performed in a rotating method; at the first session, thus, the first patient had an ice massage, whereas the second patient had a warm pack massage at the same session. Sampling was carried out for three months. Pain related to needle insertion was measured after four types of interventions on the Huko acupoint including ice massage warm massage, using 37 degrees centigrade water and after routin method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051122210N1**

Registration date: **2015-08-23, 1394/06/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-23, 1394/06/01

Registrant information

Name

Masoumeh Kavianpoor

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2014-08-19, 1393/05/28

Expected recruitment end date

2014-11-17, 1393/08/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of cold and heat stimulation of the Hoku point on pain of needling arteriovenous fistulas in elderly patients undergoing hemodialysis

Public title

Comparing the effect of cold and heat massage of the Hoku point on pain of needling arteriovenous fistulas in

elderly patients undergoing hemodialysis

Purpose
Supportive

Inclusion/Exclusion criteria
inclusion criteria: being in ages of 60 years and over; being under regular hemodialysis; willingness to participate in the study; having no impairment in consciousness and vision; being able to communicate verbally; having no pain before hemodialysis session; not using any opiate or analgesic drugs at least 4 hours before the hemodialysis session; not having a known dementia; peripheral vascular disorder and diabetic neuropathy; lack of any inflammation bite or fracture on the massage location or the Huko point; and lack of any complications in the AVF (i.e. thrombosis; infection; aneurysm). The exclusion criteria were requiring more than one attempt to establish a needle in the AVF in hemodialysis session; a decision to withdraw from the study; the incidence of any problems in the Huko point; and occurrence of any local complications in the AVF (i.e. thrombosis; infection; and aneurysm) during the study.

Age
From **60 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Ghotb Ravandi Blvd, Kashan

City

kashan

Postal code

009887155/11

Approval date

2014-08-13, 1393/05/22

Ethics committee reference number

p/29/5/1/2563

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 and after the intervention.

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Local complications, fistula

Timepoint

Before and during the intervention.

Method of measurement

Check fistula

Intervention groups

1

Description

In the first type of intervention, a 50 mL plastic bottle made of polyethylene with a child-proof lock, containing ice was placed on the Huko point of the hand without an AVF and moved slowly on a rotating basis for ten minutes before needling of the AVF and continued during needle insertion till the nurse fixed the needles. The level of pain using the Visual Analogue Scale was recorded by the patient. The second intervention was the same as the first on except that the bottle contained 50 mili Literof warm water with a temperature of 43-45 degree centigrade. The third intervention was also the same except that the bottle contained 50 mL of 37 degree centigrade water. The last time without interference and to control the amount of pain was measured.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhavan Hospital

Full name of responsible person

Masoumeh Kavianpoor

Street address

Abazar Street

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholam Ali Hamidi

Street address

Ghotb Ravandi Blvd, Kashan

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Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Masoumeh Kavianpoor

Position

Master Of Nursing Science Student

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