Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A Comparative Study of the Effects of Ice Massage and Shiatsu Applied to the Hegu Point on Pain and Anxiety Associated with Arteriovenous Fistula Needle Insertion in Hemodialysis Patients: A Clinical Trial

Protocol summary

Study aim

A Comparative Study of the Effects of Ice Massage and Shiatsu at the Hegu Point on Pain Intensity and Anxiety Caused by Needle Insertion into the Fistula in Patients Undergoing Hemodialysis

Design

This study is a three-arm randomized parallel clinical trial (1:1:1) in which 72 patients are allocated to Shiatsu massage, ice massage, and control groups using stratified permuted block randomization.

Settings and conduct

This clinical trial is conducted in the hemodialysis unit of Towhid Hospital, Sanandaj. Owing to the nature of the interventions (Shiatsu massage and ice application at the Hegu point), full blinding is not feasible; therefore, participants and intervention providers are aware of the treatment type, while to minimize potential bias, the outcome assessor and data analyst remain blinded to group allocation.

Participants/Inclusion and exclusion criteria

Patients aged 18–65 years undergoing hemodialysis with a stable arteriovenous fistula, without substance abuse, use of medications affecting pain or anxiety, or disorders of pain perception, will be enrolled in the study and will be withdrawn in the event of clinical instability or increased risk of fistula thrombosis.

Intervention groups

Shiatsu Group: Vertical thumb pressure is applied at the LI-4 point on the non-fistula hand with an intensity of 2–3 kg/cm² for 40 minutes (four 5-minute cycles with 2-minute rest intervals). Ice Massage Group: A cold gel pack (0 to −4°C) is applied to the LI-4 point for a duration equivalent to that of the Shiatsu group. Control Group: A sham intervention is administered at the TE5 point on the posterior forearm in the form of light pressure, with a contact duration comparable to that of the intervention groups.

Main outcome variables

The level of pain and anxiety associated with arteriovenous fistula needle insertion in patients undergoing hemodialysis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160625028627N9**
Registration date: **2026-05-11, 1405/02/21**
Registration timing: **prospective**

Last update: **2026-05-11, 1405/02/21**
Update count: **0**

Registration date

2026-05-11, 1405/02/21

Registrant information

Name
Golnaz Azami
Name of organization / entity
Medical University of Ilam
Country
Iran (Islamic Republic of)
Phone
009884133336766 & 0060389400975
Email address
gs41829@student.upm.edu.my

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2026-08-23, 1405/06/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparative Study of the Effects of Ice Massage and Shiatsu Applied to the Hegu Point on Pain and Anxiety Associated with Arteriovenous Fistula Needle Insertion in Hemodialysis Patients: A Clinical Trial

Public title
A Comparative Study of the Effects of Ice Massage and Shiatsu Applied to the Hegu Point on Pain and Anxiety
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Treatment history: No history of receiving Shiatsu or ice massage therapy within the past six months. Dialysis regimen: Receiving at least two hemodialysis sessions per week via an arteriovenous fistula. Fistula stability: At least three months have elapsed since the creation of the fistula. Substance use status: No use of narcotic drugs or alcohol, as confirmed by self-report and review of the medical record. Medication use: No use of analgesic medications (including NSAIDs and opioids) or anxiolytic drugs (such as benzodiazepines) within 24 hours prior to the dialysis session Neurological-sensory status: No sensory impairment or neuropathy in the limb with the fistula. Anatomical status: No wound, deformity, or infection at the Hegu point. Psychological status: No diagnosis of active psychiatric disorders, such as severe depression or anxiety disorders, that could affect pain perception, based on evaluation of the patient's medical record. Comorbid conditions: No chronic diseases affecting pain threshold, such as uncontrolled diabetes or neuropathy. Type of fistula: Limited to patients with radial or brachial fistulas. Smoking status: No cigarette smoking within two hours prior to the intervention due to the potential effects of nicotine on pain perception.
Exclusion criteria:
Clinical status: Occurrence of hemodynamic instability, including severe hypotension, arrhythmia, or other critical conditions during the study. Fistulas at risk of thrombosis. Willingness to continue participation: Withdrawal of the patient from further participation at any stage of the study.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized
Randomization description
To control for confounding variables and ensure balance across the intervention groups, a stratified block randomization method will be employed. The unit of randomization is the individual, with each participant independently assigned to a study group. Participants will first be stratified based on four primary variables: age (<50 vs. ≥50 years), sex (male vs. female), fistula type (radial vs. brachial), and duration of fistula use (<1 year vs. ≥1 year). The combination of these variables results in 16 distinct strata. For each stratum, random blocks of size six will be utilized, ensuring that within each block, two participants are allocated to each of the three study arms: the Shiatsu massage group, the ice pack group, and the control group. The allocation sequences will be generated using Random Allocation Software (version 2.0). To minimize bias, these sequences will be produced by an independent individual who is not involved in the executive team, data collection, or intervention delivery. To ensure allocation concealment, the generated sequences will be placed in opaque, sequentially numbered, and sealed envelopes, which will be stored in a secure location. Following the screening process and the acquisition of informed consent from eligible patients, their demographic and clinical data will be recorded. Each participant will then be assigned to the appropriate stratum based on their characteristics. Subsequently, the corresponding envelope for that stratum will be opened in numerical order, and the participant will be assigned to a study group according to the predetermined sequence
Blinding (investigator's opinion)
Single blinded
Blinding description
In this clinical trial, due to the nature of the interventions under investigation (Shiatsu massage and application of an ice pack at the Hegu point), complete blinding of participants and intervention providers is not feasible. Therefore, participating patients and healthcare personnel responsible for delivering the intervention will be aware of the type of intervention administered. However, to minimize observer and analytical bias, specific measures have been implemented to ensure blinding at the stages of outcome assessment and data analysis. Accordingly, the outcome assessor, who is responsible for recording and collecting data related to pain intensity and anxiety levels, will be blinded to the participants' group allocation. The outcome assessor will not be involved in the randomization process or in the implementation of the interventions and will complete the measurement instruments solely based on participants' identification codes. In addition, the data analyst will also be blinded to group allocation. The randomization process and assignment of participants to study groups will be performed by a researcher who is not involved in outcome assessment or data analysis. Consequently, in this study, blinding is implemented at the levels of outcome assessment and data analysis in order to reduce the risk of bias in the recording and interpretation of the results.

Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciecnes, Sanandaj, Iran
Street address
No. 1, Pasdaran St., Pasdaran Blvd
City
Sanandaj
Province
Kurdistan
Postal code
6931934833
Approval date
2026-04-13, 1405/01/24
Ethics committee reference number
IR.MUK.REC.1405.014

Health conditions studied

1

Description of health condition studied
hemodialysis patients
ICD-10 code
Z49.31
ICD-10 code description
Encounter for adequacy testing for hemodialysis

Primary outcomes

1

Description
Pain intensity associated with arteriovenous fistula needle insertion in hemodialysis patients: Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. In this study, pain refers to the unpleasant sensation caused by stimulation of nociceptive nerves in the fistula area following needle insertion during hemodialysis. Pain intensity will be measured using the Numeric Rating Scale (NRS), a ratio-scale instrument ranging from 0 (no pain) to 10 (worst imaginable pain). Participants will be asked to rate their pain immediately after cannulation of the arteriovenous fistula.
Timepoint
The intensity of pain associated with arteriovenous fistula needle insertion will be measured in all three study groups (Shiatsu massage, ice massage, and control) over two consecutive days, at a standardized time point each day. On the first day, without any intervention, participants' pain intensity will be assessed immediately after cannulation of the arteriovenous fistula using the Numeric Rating Scale (NRS). On the second day, the assigned intervention for each group (Shiatsu massage, ice massage, or sham intervention at point TE5) will be performed for 40 minutes, starting 20 minutes before the scheduled cannulation, and subsequently, as on the first day, pain intensity will be measured immediately after cannulation using the NRS scale.
Method of measurement
Pain intensity resulting from needle insertion into the arteriovenous fistula will, in this study, be defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. To assess pain intensity, the numerical rating scale will be used. This instrument is a ratio scale with a range from zero, representing no pain, to ten, representing the worst imaginable pain. After arteriovenous fistula cannulation, participants will report their pain intensity by selecting a number between zero and ten. All recorded values will be collected and coded by the outcome assessor using the study's standardized forms.

2

Description
Anxiety is defined as an unpleasant emotional state characterized by feelings of tension, worry, distressing thoughts, and physiological changes such as increased autonomic nervous system activity. In this study, anxiety refers to the feeling experienced by patients in relation to the process of arteriovenous fistula cannulation and the performance of hemodialysis. Anxiety severity will be measured using the Spielberger State Anxiety Questionnaire. This instrument is a standardized scale for assessing an individual's current anxiety, and the score obtained reflects the patient's level of state anxiety at the time of assessment. Participants will be asked to complete the questionnaire at the time point specified in the study protocol.
Timepoint
Evaluation of the primary outcomes, including anxiety level, will be conducted at two distinct time points as follows:1. Day 1 (Baseline phase):Pain intensity: Immediately after arteriovenous fistula cannulation, without any intervention being administered on this day.State anxiety: Sixty minutes after arteriovenous fistula cannulation.2. Day 2 (Post-intervention phase):Pain intensity: Immediately after arteriovenous fistula cannulation, following the 40-minute intervention in the Shiatsu massage, ice massage, or control (sham intervention) groups, which begins 20 minutes prior to cannulation.State anxiety: Sixty minutes after arteriovenous fistula cannulation, following the sequence of intervention.
Method of measurement
In this study, patients' anxiety will be assessed using the Spielberger State Anxiety Questionnaire. This questionnaire is a standardized instrument designed to

measure the individual’s current level of anxiety at the time of assessment, and the score obtained from it will indicate the level of state anxiety experienced by the patient in relation to arteriovenous fistula cannulation during hemodialysis sessions. This instrument will be used as the method for measuring the anxiety variable in the present study, and its level of measurement will be considered a ratio scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, the intervention will be administered as Shiatsu massage applied to the Hegu point on the non-fistula hand. The Hegu point is located in the space between the first and second metacarpal bones, at the proximal half of the second metacarpal bone, over the first dorsal interosseous muscle. The intervention will be performed by a trained therapist using vertical thumb pressure applied at a 90-degree angle to the skin surface. The pressure intensity will be adjusted to produce relative blanching of the therapist’s nail bed and will be approximately equivalent to 2 to 3 kilogram-force per square centimeter, without causing significant discomfort to the patient. The approximate depth of pressure penetration into the subcutaneous tissue will be 1 to 1.5 centimeters. The intervention will be administered for a total duration of 20 minutes, divided into four 5-minute cycles with 2-minute rest intervals between cycles.:

Category

Prevention

2

Description

Intervention group 2: In this group, the intervention will consist of ice massage applied to the Hegu (LI-4) point on the non-fistula hand. For this purpose, standardized medical gel packs with dimensions of 5 × 5 cm and a thickness of 1 cm will be used. Prior to application, the surface temperature of the gel pack will be adjusted within the range of 0 to −4°C. The ice pack will be placed within a thin sterile cotton covering and gently applied to the Hegu point using very light pressure. The total intervention duration will be 20 minutes, administered in four 5-minute cycles, with a 2-minute rest period between cycles.

Category

Prevention

3

Description

Control group: In this group, patients will receive a control intervention consisting of very light, superficial contact without specific pressure stimulation applied to the TE5 point (Tianchuan), located on the dorsal aspect of the non-fistula forearm. The precise location of this point is approximately two finger widths proximal to the wrist crease, situated between the radius and ulna bones. This contact involves only the therapist’s stationary hand placement without exerting any pressure or deep stimulation, ensuring that no significant pressure or sensory activation occurs. The duration of skin contact with the therapist’s hand in this group will be identical to that of the intervention groups (Shiatsu and ice massage), lasting 40 minutes divided into four 5-minute cycles with 2-minute rest intervals between cycles.The purpose of this control design is to eliminate nonspecific effects of tactile contact and therapist presence, maintaining equivalent contact duration and exposure time, while preventing any pressure application or activation of pain thresholds or acupuncture points. This approach allows a valid assessment of the specific effects of Shiatsu massage and ice massage interventions.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Tohid Hospital & Medical Training Center, Sanandaj

Full name of responsible person
Dr. Golnaz Azami

Street address
No. 1, Pasdaran St., Pasdaran Blvd

City
Sanandaj

Province
Kurdistan

Postal code
6931934833

Phone
+98 918 344 6450

Email
golnaz.azami64@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sanandaj University of Medical Sciences

Full name of responsible person
Dr. Afshin Maleki

Street address
No. 1, Pasdaran St., Pasdaran Blvd

City
Sanandaj

Province
Kurdistan

Postal code
6931934833

Phone
+98 918 344 6450
Email
golnaz.azami64@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sanandaj University of Medical Sciences
Proportion provided by this source
60
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
Sanandaj University of Medical Sciences
Full name of responsible person
Dr. Golnaz Azami
Position
Assistant Professor and Faculty Member, Kurdistan University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
No. 1, Pasdaran St., Pasdaran Blvd
City
Sanandaj
Province
Kurdistan
Postal code
6931934833
Phone
+98 87 3366 4664
Email
golnaz.azami64@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Dr. Golnaz Azami
Position
Assistant Professor and Faculty Member, Kurdistan University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
No. 1, Pasdaran St., Pasdaran Blvd
City
Sanandaj
Province
Kurdistan
Postal code
6931934833
Phone
+98 87 3366 4664
Email
golnaz.azami64@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Dr. Golnaz Azami
Position
Assistant Professor and Faculty Member, Kurdistan University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
No. 1, Pasdaran St., Pasdaran Blvd
City
Sanandaj
Province
Kurdistan
Postal code
6931934833
Phone
+98 87 3366 4664
Email
golnaz.azami64@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
Yes - There is a plan to make this available
Title and more details about the data/document
Title of Data/Documents: Clinical Trial Dataset on Pain and Anxiety Measures During Arteriovenous Fistula

Needle Insertion in Hemodialysis Patients: Effects of Shiatsu and Ice Massage Interventions Details: This dataset comprises anonymized individual participant data collected during a randomized clinical trial investigating the effects of Shiatsu massage, ice massage, and a control intervention on pain intensity and anxiety levels associated with arteriovenous fistula (AVF) needle insertion in hemodialysis patients. The data include demographic characteristics, clinical inclusion/exclusion criteria, randomization strata, intervention adherence, and primary (pain intensity measured by Numeric Rating Scale) and secondary outcomes (state anxiety assessed by the Spielberger State Anxiety Inventory). All personal identifiers have been removed or masked according to established de-identification protocols to ensure participants' confidentiality and privacy. Therefore, the full dataset is potentially shareable with authorized researchers for secondary analyses following appropriate data use agreements. Certain sensitive variables related to patient comorbidities and medication history are included but anonymized. Access to data will be granted under controlled conditions to protect patient confidentiality. If data sharing is limited to specific variables (e.g., only primary outcomes or summary data), please specify accordingly.

When the data will become available and for how long

Data will be available 6 months post-publication.

To whom data/document is available

The study data and documents will be accessible to both of the following groups: A) Academic researchers: University faculty members, Research institute scientists, Graduate students (with supervisor approval).

Under which criteria data/document could be used

Access to de-identified data and study documents is subject to the following requirements: a) General Conditions: Submission of formal request including research objectives, analysis plan and timeline, Approval by the ethics committee of requester's institution, Signed limited data use agreement. b) Analytical Restrictions: Any statistical analysis is permitted provided it doesn't enable indirect identification, Subgroup comparisons require minimum 10 cases per group, Machine learning applications need separate approval. c) Usage Permissions: Permitted for academic research and therapeutic protocol development, Commercial use requires separate licensing agreement, Educational materials may be redistributed with proper attribution. d) Oversight Mechanisms: Mandatory progress reports every 6 months, Periodic audits by independent data monitor, Data deletion commitment after project completion.

From where data/document is obtainable

Applicants can request data and study documentation by sending an email to the following address: golnaz.azami64@gmail.com

What processes are involved for a request to access data/document

Request Procedure: Formal Request Submission: Complete request form (if applicable), Email to golnaz.azami64@gmail.com with clear subject. Attach: -Research proposal, -Ethics approval, -Affiliation documents. *Initial Review (3-5 business days): -Document completeness check, -Research objectives alignment assessment, *Technical Evaluation (7-10 business days): -Analysis plan review by technical team, -Access level determination, -De-identified data preparation. *Agreement Finalization (5-7 business days): -NDA signing, -Usage terms confirmation. -Cost determination (if applicable). *Data Delivery (2-3 business days post-agreement): -Secure platform transfer, -User guide provision, -Analysis restrictions specification, Total Processing Time: 15-25 business days (depending on request complexity).

Comments