Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2026

Rhythmic Breathing Integrated with Hugo Point Acupressure V.S. Vapocoolant Spray on Pain Intensity During Needle Insertion into Arteriovenous Fistula in Hemodialysis Patients:A Randomized Controlled Trial

Protocol summary

Study aim

Compare combination of rhythmic breathing with Hugo point acupressure versus vapocoolant spray in reducing pain during needle insertion.

Design

An experimental design will be conducted to compare Rhythmic Breathing combined with Hugo Point Acupressure versus vapocoolant spray in alleviating pain. A total of 120 participants will be included in the study, with 24 participants in each group.

Settings and conduct

In Dhi Qar Governorate, Iraq, covering several hemodialysis centers, including Al-Hussein Center, Souq Al-Shuyukh Dialysis Center. The study will involve over 500 male patients aged 18 years or older, aiming to assess both administrative needs and the accessibility of the research population.

Participants/Inclusion and exclusion criteria

Inclusion criteria :male hemodialysis patients aged 18+, with an arteriovenous fistula, alert, able to speak, not taking analgesics. Exclusion criteria:with unrelated severe pain, allergies to vapocoolant spray, recent surgery near the fistula, cognitive impairments, infections at the fistula site, or inflammation at the Hugo point.

Intervention groups

Rhythmic Breathing: Participants will practice deep breathing for two minutes before and during needle insertion, inhaling, holding, and exhaling for a count of three. Hugo Point Acupressure: The Hugo Point on the hand will be massaged with moderate pressure for two minutes before and during needle insertion, using a cycle of 10 seconds of pressure and 2 seconds of rest. Combination of Rhythmic Breathing and Acupressure: Both techniques will be applied together for two minutes before and during needle insertion. Vapocoolant Spray: The spray will be applied to the skin for 3-4 seconds, followed by a 10-second evaporation, before needle insertion.

Main outcome variables

Pain Intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241103063578N1**
Registration date: **2024-11-23, 1403/09/03**
Registration timing: **prospective**

Last update: **2024-11-23, 1403/09/03**
Update count: **0**

Registration date

2024-11-23, 1403/09/03

Registrant information

Name

Hassan Raysan Mohammed

Name of organization / entity

University of Baghdad

Country

Iraq

Phone

+964 780 628 6907

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-01, 1403/09/11

Expected recruitment end date

2025-03-21, 1404/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Rhythmic Breathing Integrated with Hugo Point Acupressure V.S. Vapocoolant Spray on Pain Intensity During Needle Insertion into Arteriovenous Fistula in Hemodialysis Patients:A Randomized Controlled Trial

Public title

Rhythmic Breathing Integrated with Hugo Point Acupressure V.S. Vapocoolant Spray on Pain Intensity During Needle Insertion into Arteriovenous Fistula in Hemodialysis Patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The participants must be male individuals who are receiving regular hemodialysis treatment Alertness The individuals participating in this study are required to be a minimum of 18 years old or older Ability to speak The participants are required to possess an arteriovenous fistula that serves as the access point for dialysis. Participants who do not take analgesics Not having diabetes for over 10 years

Exclusion criteria:

Patients who are experiencing severe pain or discomfort that is not associated with the needle insertion procedure are to be excluded Patients who have documented allergies or hypersensitivity reactions to vapocoolant spray Patients who have undergone recent surgical procedures or have experienced trauma in proximity to the arteriovenous fistula are disqualified Patients exhibiting cognitive impairment or mental health disorders that may hinder their ability to comprehend instructions or provide informed consent Patients presenting with active infections or complications at the site of the arteriovenous fistula Inflammation or injury at the Hugo point .

Age

From **18 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling methodology encompasses a dual-phase procedure designed to procure representative constituents of the target population, specifically male patients undergoing hemodialysis who are subjected to needle insertion into arteriovenous fistulas. In the initial phase, researcher will disseminate two distinct categories of cards: one denoting the patient's eligibility for participation in the study (orange), and the other signifying ineligibility (gray). Patients who are in possession of the eligible card will subsequently select from one of five colored cards , each representing a different study condition: White = Control group Yellow = Rhythmic breathing only Green = Hugo point acupressure only Blue = Vapocoolant spray only red = Rhythmic breathing integrated with Hugo point acupressure

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

Ethics committee in college of nursing at University of Baghdad

Street address

Bab-ALMuadham

City

Baghdad

Postal code

10053

Approval date

2024-10-28, 1403/08/07

Ethics committee reference number

5

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

Primary outcome variable is the level of pain, which can be altered based on the Hugo point acupressure, Rhythmic breathing, and vapocoolant spray.

Timepoint

Two minute before needle insertion and during insertion

Method of measurement

Visual analog scale (VAS) will be use to assess intensity of pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Rhythmic Breathing: Participants will practice deep breathing for 2 minutes before needle insertion, inhaling, holding, and exhaling for 3 seconds each. The exercise continues during needle insertion.Hugo Point Acupressure: The non-inserted hand will receive circular massage on the Hugo point for 2 minutes before and during needle insertion, with pressure applied for 10 seconds followed by 2 seconds of rest.Rhythmic Breathing + Hugo Point Acupressure: Participants will combine both interventions, engaging in rhythmic breathing while receiving Hugo point acupressure for 2 minutes before and during needle insertion.Vapocoolant Spray: The spray will be applied to the skin for 3-4 seconds, followed by a 10-second evaporation period before needle insertion.Pain intensity will be evaluated immediately after needle insertion in all interventions.

Category

Other

2

Description

Control group: Control For the control group, no interventions will be done, and the pain will assess immediately after needle insertion in arteriovenus fistula

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Hussein Center for Dialysis

Full name of responsible person

Hassan Raysan Mohammad

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Al-Nasiriyah

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Recruitment center

Name of recruitment center

Souq Al-Shuyukh Dialysis Center

Full name of responsible person

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Recruitment center

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Imam Hassan Al-Mujtaba Hemodialysis Unit

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

College of Nursing, University of Baghdad

Full name of responsible person

Assistant Professor Wafaa Abdul Ali Hattab

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Grant name

Grant code / Reference number

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

No

Title of funding source

The author of the trial is the funding source

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

University of Baghdad, College of Nursing

Full name of responsible person

Hassan Raysan Mohammad

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Adults Nursing

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Person responsible for scientific inquiries

Contact

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Latest degree

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The researcher is acknowledging the scientific community to have verifiable findings of the study.
sharing plan includes making all the related data available through publishing the study report in peer-reviewed reputable journals.
When the data will become available and for how long
God willing, once finishing the process of data collection, analysis and successfully publishing the manuscript, all the related files will become available for 6 months after publications
To whom data/document is available
All the related files will be shared with any scientific interested parties.
Under which criteria data/document could be used
It may be used after seeking the author's permission and acknowledging his contribution.
From where data/document is obtainable
The author's professional e-mail that will be available with the published manuscript can be used to contact the author. e-Mail: Hasan.band2302m@conursing.uobaghdad.edu.iq
What processes are involved for a request to access data/document
N/A
Comments
Profound appreciations are due to the IRCT members for their genuine efforts in helping researchers fulfilling their academic endeavors.