

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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

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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 arteriovenous 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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2

Recruitment center

Name of recruitment center

Souq Al-Shuyukh Dialysis Center

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Imam Hassan Al-Mujtaba Hemodialysis Unit

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4

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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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Web page address

<https://g.co/kgs/1AbtJ2H>

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.