

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Comparison of the effects of aromatherapy with salvia officinalis and lavender essential oil on vascular needle insertion pain in hemodialysis patients

Protocol summary

Study aim

Comparison of the effect of aromatherapy with salvia officinalis and lavender essential oil on the intensity of pain during the insertion of vascular needles in hemodialysis patients.

Design

The clinical trial is conducted in three groups in a crossover, one-sided blind, randomized, on 30 hemodialysis patients. The rand function of Excel software was used for randomization.

Settings and conduct

This study is conducted in the hemodialysis department of Motamedi Hospital in Garmsar. The samples are selected by easy sampling according to the inclusion and non-entry criteria and are studied randomly in 3 ways: lavender scent, salvia officinalis scent, and placebo. Samples are not aware of the type of scent.

Participants/Inclusion and exclusion criteria

Age over 20 years
Olfactory health
No history of asthma
Not using perfume and cologne
No drug addiction
Absence of severe pain in other parts of the body

Intervention groups

In each of the aromatherapy methods (lavender, sage), the client inhales the aroma 10 minutes before and during arterial needling. In the placebo method, the patient smells the scent of water 10 minutes before and during the injection.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110430006342N15**
Registration date: **2023-05-23, 1402/03/02**

Registration timing: **prospective**

Last update: **2023-05-23, 1402/03/02**

Update count: **0**

Registration date

2023-05-23, 1402/03/02

Registrant information

Name

Ali Asghar Ghods

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-05, 1402/03/15

Expected recruitment end date

2023-10-07, 1402/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of aromatherapy with salvia officinalis and lavender essential oil on vascular needle insertion pain in hemodialysis patients

Public title

Comparing the effects of lavender and salvia officinalis on pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with arteriovenous fistula for more than 3 months

Exclusion criteria:

Age under 20 years
Absence of drug addiction
Absence of severe pain in other parts of the body
Unhealthy sense of smell
No history of asthma
Not using perfume and cologne
No drug addiction
Absence of severe pain in other parts of the body

Age

From 20 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

The samples, which are 30 people and are fixed in all three groups, will randomly receive one of the 3 interventions at different times of visit. For this purpose, using RAND Excel, 30 blocks of 3 that show the order of intervention methods were randomly designed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Aromatherapy is performed by the researcher. Arterial needling is performed by a skilled nurse, and a visual analog scale of pain sheet will be given to the patients by another nurse who does not know about the type of scent to record their pain.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

Street address

Deputy of research and technology, Central Headquarters of Semnan University of Medical Sciences, Basij Boulevard

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Semnan

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Semnan

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3519899951

Approval date

2023-05-01, 1402/02/11

Ethics committee reference number

IR.SEMUMS.REC.1402.017

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

pain severity

Timepoint

Immediately after arterial puncture in hemodialysis

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Pulse

Timepoint

5 minutes before the intervention and immediately after the intervention

Method of measurement

Sairan vital signs monitor device

2

Description

Respiration

Timepoint

5 minutes before the intervention and immediately after the intervention

Method of measurement

Sairan vital signs monitor device

3

Description

Blood Pressure

Timepoint

5 minutes before the intervention and immediately after the intervention

Method of measurement

Sairan vital signs monitor device

Intervention groups

1

Description

Intervention group: »Lavender scent. 4 drops of 100% lavender essential oil prepared by Shazdeh company are dripped on a layer of gauze and placed on the patient's neck at a distance of about 20 cm from the nose.

Category

Prevention

2

Description

Intervention group: salvia officinalis scent. 4 drops of 100% salvia officinalis essential oil prepared by Shazdeh company are dripped on a layer of gauze and placed on the patient's neck at a distance of about 20 cm from the nose.

Category

Prevention

3

Description

Control group: Placebo. 4 drops of water are dripped on a layer of gauze and placed on the patient's neck at a distance of about 20 cm from the nose.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Motamedi Hospital in Garmsar

Full name of responsible person

Ali Asghar Ghods

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan University of Medical Sciences

Proportion provided by this source

50

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

Semnan University of Medical Sciences

Full name of responsible person

Faezeh Ashori

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

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

Only information related to the main outcome can be shared.

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

All researcher

Under which criteria data/document could be used

Mention the source of use

From where data/document is obtainable

Ali Asghar Ghods aaghods@yahoo.com

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

The data will be sent one month after the request

Comments