Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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 addiction8) 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

City

Semnan

Province

Semnan

Postal code

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 warter 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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Faculty of Nursing, Semnan University of Medical Sciences, Km 6 Damghan Road
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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
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Full name of responsible person
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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