Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of aromatherapy with Lavender essence on pain from the fistula needle in patients undergoing hemodialysis

Protocol summary

Summary

Objective; this study is performed to assess the effect of inhalation aromatherapy with Lavender essence on the pain caused by arteriovenous fistula puncture in hemodialysis patients. Design; this study is a controlled randomized clinical trial. Setting and conduct; Nineteen eligible patients will be randomly placed in experimental and control groups. Demographic and clinical characteristics of the patients will be recorded with questionnaire. Patient including major criteria; 3 times a week dialysis; being over 18; alertness and ability to communicate and having a good sense of smell. Patient eligibility major criteria; candidate for a transplant; pregnancy; record of allergies; chronic respiratory diseases; using analgesic in 3 hours and drug addiction. Intervention; ninety two hemodialysis patients with AVF will be randomly divided into two groups. In the first time, the fistula needle pain will be measured with Visual Analogue Scale (VAS) in two groups. The experimental group will be inhaled with 10% lavender essence for five minutes in three consecutive dialysis sessions but the control group will be inhaled the placebo. Patients ' pain will be measured after three interventions in each group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307047494N6**
Registration date: **2013-07-21, 1392/04/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-07-21, 1392/04/30

Registrant information

Name

Masoumeh Bagheri Nesami

Name of organization / entity

Mazandaran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences.

Expected recruitment start date

2013-06-20, 1392/03/30

Expected recruitment end date

2013-07-21, 1392/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with Lavender essence on pain from the fistula needle in patients undergoing hemodialysis

Public title

The effect of aromatherapy with Lavender essence on pain from the fistula needle in patients undergoing hemodialysis

Purpose

Health service research

Inclusion/Exclusion criteria

Patient including major criteria; 3 times a week dialysis; being over 18; alertness and ability to communicate and

having a good sense of smell. Patient eligibility major criteria; candidate for a transplant; pregnancy; record of allergies; chronic respiratory diseases; using analgesic in 3 hours and drug addiction

Age

From **18 years** old to **130 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Science

Street address

Moalem Street, Moalem Square, Sari .

City

Sari

Postal code

4816715793

Approval date

2013-05-29, 1392/03/08

Ethics committee reference number

334 - 91

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

Z49

ICD-10 code description

Care involving dialysis

Primary outcomes

1

Description

The pain from the fistula needle

Timepoint

Before intervention and after 3 interventions

Method of measurement

Visual Pain Scale

Secondary outcomes

1

Description

Allergic to Lavender

Timepoint

To 6 days after the first intervention.

Method of measurement

Side effects of the drug and the patient's questions

Intervention groups

1

Description

On the first day of the study (before the intervention), the pain from the fistula needle will be measured and recorded. Experimental group: experimental group will be exposed to the inhalation of lavender essence produced by Barij certified pharmaceutical company with quality standards of ISO 9001 and ISO / IEC 17025 at a concentration of 10% for 3 consecutive times (once for each hemodialysis). Lavender essence is produced from fresh flowering parts of the plant which contains Linalool, Linalool acetate, Caffeic acid and Tannins. Since pure lavender essence is highly concentrated and its use irritates the patients, the essence is diluted with sweet almond oil with one in- ten proportion and 10% compound is produced. A total of 3 interventions during three sessions of dialysis will be performed. Thus, a cotton ball soaked with 3 drops of lavender essence with concentration of 10% will be put at a distance of 10 cm and the patient will be asked to breathe slowly for 5 minutes . Fistula is then punctured. Needles used are the same for all patients taken from Soha Company with the number of BNO: P 948115 A MFG. In each intervention, the VAS pain scale is measured after aromatherapy.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group will be treated by the above method under aromatherapy with placebo. The placebo is produced by Barij Essence Company and include a base combination of an aromatherapy without lavender. For the preparation of the compound, one drop of the lavender essence is poured into the base solution which is sweet almond oil

to make it dilute and cause it to have the same smell without having its properties.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari Emam Khomeini hospital

Full name of responsible person

Dr Masoumeh Bagheri- Nesami

Street address

School of Nursing & Midwifery Mazandaran University of Medical Sciences Sari, Iran.

City

Sari

2

Recruitment center

Name of recruitment center

Sari Fatima Zahra hospital

Full name of responsible person

Dr Masoumeh Bagheri- Nesami

Street address

Mazandaran University of Medical Sciences, Juibar, Sari.

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research Mazandaran University of Medical Sciences.

Full name of responsible person

Dr Ahmad Ali Enayeti

Street address

Vice Chancellor for research Mazandaran University of Medical Sciences, Moalem Street ,Moalem Square,Sari, Iran..

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research Mazandaran University of Medical Sciences.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Science

Full name of responsible person

Dr Mohamad Ali Heydari Gorji

Position

Phd- faculty

Other areas of specialty/work

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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty