Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of aromatherapy with lavender Essential oil on anxiety, depression and fatigue, in hemodialysis patients

Protocol summary

Summary

The purpose of this study is to determine the effect of aromatherapy with lavender essence on anxiety, depression and fatigue in patients undergoing hemodialysis Patient including major criteria: at least 6 months of dialysis treatment; dialysis for 3 times a week; being over 18 years; alertness and ability to communicate; having a good sense of smell; have not a stressful event in the past 6 months; don't using sedatives drugs. Patient eligibility major criteria: candidate for a transplant; pregnancy or decision to pregnancy; record of allergies; chronic respiratory diseases; addiction At the baseline demographic and clinical data will be collected using check list and questionnaires. Fatigue severity will be measured using Fatigue Severity Scale. Assessment of anxiety and depression in patients will be done with hospital anxiety and depression questionnaire. Well being will be measured using VAS scale. 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 . 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. In experimental group a cotton ball soaked with 2 drops of lavender essential oil with concentrations of 10% in the first week (3 first session), 20% in the second week (3 second session), 30% in the third week (3 third session), 40% in the week fourth (3 fourth session) and 50% in the fifth week (3 fifth sessions) attached to his collar and he will be asked to breathe normally for 20 minutes.: Patients in the control group will be received usual care.anxiety, depression ,fatigue and well being questionnaire will be complete in the end of each week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201505257494N12**
Registration date: **2015-12-10, 1394/09/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-12-10, 1394/09/19

Registrant information

Name
Masoumeh Bagheri Nesami
Name of organization / entity
Mazandaran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research Mazandaran University of Medical Sciences.

Expected recruitment start date

2015-06-20, 1394/03/30

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of aromatherapy with lavender Essential oil on anxiety, depression and fatigue, in hemodialysis patients

Public title
Effect of lavender on anxiety, depression and fatigue in hemodialysis patients

Purpose
Health service research

Inclusion/Exclusion criteria
Patient including major criteria: at least 6 months of dialysis treatment; dialysis for 3 times a week; being over 18 years; alertness and ability to communicate; having a good sense of smell; have not a stressful event in the past 6 months; don't using sedatives drugs Patient eligibility major criteria: candidate for a transplant; pregnancy or decision to pregnancy; record of allergies; chronic respiratory diseases; addiction

Age
From **18 years** old to **100 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **38**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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 of Mazandaran University of Medical Science

Street address
Moalem Street, Moalem Square, Sari

City
Sari

Postal code

Approval date
2015-09-23, 1394/07/01

Ethics committee reference number
IR.MAZUMS.REC.94

Health conditions studied

1

Description of health condition studied
hemodialysis patient

ICD-10 code
Z49.0

ICD-10 code description
Care involving dialysis

Primary outcomes

1

Description
depression and anxiety

Timepoint
Before intervention first week, second week,third week, fourth week and fifth week

Method of measurement
Hospital Anxiety and Depression Scale

2

Description
fatigue

Timepoint
Before intervention first week, second week,third week, fourth week and fifth week

Method of measurement
Fatigue Severity Scale

3

Description
well being

Timepoint
Before intervention first week, second week,third week, fourth week and fifth week

Method of measurement
visula Analogue scale

Secondary outcomes

1

Description
Allergic to Lavender

Timepoint
During five weeks of intervention

Method of measurement
Questions from Patients

Intervention groups

1

Description
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. 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. In experimental group a cotton ball soaked with 2 drops of lavender essential oil with concentrations of 10% in the first week (3 first session), 20% in the second week (3 second session), 30% in the third week (3 third session), 40% in the week fourth (3 fourth session) and 50% in the fifth week (3 fifth sessions) attached to his collar and he will be asked to breathe normally for 20 minutes

Category

Treatment - Drugs

2

Description

Patients in the control group will be received usual care

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Behshahe Hospital

Full name of responsible person

Ali Mahdavi

Street address

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

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

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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 Sciences

Full name of responsible person

Attieh Nikkhah

Position

MSC in Critical Care Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate Professor

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