

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 Jul 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3336 7551

##### Email address

mbagheri@mazums.ac.ir

##### 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

##### 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 Sciences

##### Full name of responsible person

Attieh Nikkhah

##### Position

MSC in Critical Care Nursing

##### Other areas of specialty/work

##### Street address

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

##### City

Sari

##### Postal code

4815696869

##### Phone

+98 11 3337 1010

##### Fax

##### Email

atinik1357@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mazandaran University of Medical Science

##### Full name of responsible person

Dr Masumeh Bagheri Nesami

##### Position

Associate Professor

##### Other areas of specialty/work

##### Street address

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

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+98 11 3336 7345

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##### Email

anna3043@gmail.com

##### Web page address

**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*