

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### The effect of topical application of lipogel containing lavender essential oil on sleep quality and feeling good in hemodialysis patients

#### Protocol summary

##### Study aim

The effect of topical application of lipogel containing lavender essence on sleep quality and well-being of hemodialysis patients

##### Design

A randomized parallel -controlled clinical trial, double-blind,

##### Settings and conduct

This study will be performed on hemodialysis patients during dialysis. The patients in the intervention group will receive lipogel with lavender essence oil on their ankles for one minute. In the placebo group, lipogel is administered without lavender essence oil. The control group will receive routine care.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study, 18 years of age or older, with end-stage renal disease, receiving regular dialysis treatment at least three times a week for six months, having complete alertness and ability to communicate, read and write literacy, Exclusion criteria: No history of any allergies (skin and respiratory, especially essential oils and fragrances) and neurological disorders, no mental disorders (such as Down Syndrome and dementia), no experience of any stressful event in the past six months (such as death A close relative), not taking sedatives

##### Intervention groups

Intervention group: One person removed 5% of Lavandula Angustifolia essential oil from a tube of lipogel containing essential oil after wearing two grams of lipogel-containing glove and after measuring accurately with scales on one patient's legs from ankle to toe two feet in width. Pointing finger and measuring 5 cm in length by ruler uniformly, top to bottom for 1 minute. Placebo: In the above conditions, lipogel without lavender essential oil is applied to the patient's legs in the same amount and method as above. Control: There is no intervention by the research team and they receive routine care.

#### Main outcome variables

Sleep quality score and well being score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191007045019N1**

Registration date: **2020-03-10, 1398/12/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-10, 1398/12/20**

Update count: **0**

##### Registration date

2020-03-10, 1398/12/20

##### Registrant information

##### Name

Sara Vafae

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3324 3564

##### Email address

saravafae.1358@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-22, 1398/10/01

##### Expected recruitment end date

2020-04-20, 1399/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

The effect of topical application of lipogel containing lavender essential oil on sleep quality and feeling good in hemodialysis patients

## Public title

The effect of topical application of lipogel in hemodialysis patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Willingness to participate in the study 18 years of age or older End-stage kidney disease treated regularly with dialysis at least three times a week for six months with full alertness and ability to communicate, literate

### Exclusion criteria:

no history of allergies ( skin and respiratory allergies essential oils and fragrances) no history of mental illness, lack of mental disorders(such as Down syndrome and dementia), lack of experience of any stressful event in the past six months (such as death of a close relative), lack of sedative medication

## Age

From **18 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients were randomly assigned to each group using Permuted block Randomization as follows. To randomly assign people to different groups, we select 20 blocks of 6 that will be blocks from 120 different modes such as AABCC, AABCBC, AACBCB, ABCABC, BABCAC, ACBBCA. In each block there will be two cases of Group A, two cases of Group B and two cases of Group C. The computer program randomly selects one at a time, which is a random order of individuals. Considering the fact that women and men are separated in the Citizen's Center, patients are number 1 to 51 from the Citizens 'Center of the Citizens' Center, and from 52 to 102 from the Men's Ward of the Citizen Dialysis Center and the next 18 patients from the Mazandaran Heart Center

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this study, final evaluators will be blinded.

## Placebo

Used

## Assignment

Factorial

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mazandaran university of medical sciences

##### Street address

Sari, Imam Sq, Joybar 3way, Start of valiye asr highway, Mazandaran University of Medical Sciences

##### City

Sari

##### Province

Mazandaran

##### Postal code

۴۸۱۵۷۳۳۹۷۱

#### Approval date

2019-11-13, 1398/08/22

#### Ethics committee reference number

IR.MAZUMS.REC.1398.1156

## Health conditions studied

### 1

#### Description of health condition studied

renal disease

#### ICD-10 code

N01

#### ICD-10 code description

Rapidly progressive nephritic syndrome

## Primary outcomes

### 1

#### Description

Improve sleep quality

#### Timepoint

Before the intervention and four weeks after the intervention

#### Method of measurement

The quality of sleep with the Pittsburgh Instrument

### 2

#### Description

Feeling Well Using the yield Mental Feeling Tool

#### Timepoint

Before the intervention and four weeks after the intervention

#### Method of measurement

the instrument of yield feeling psychologically well

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

first Intervention group: After obtaining informed consent, during the hemodialysis while the patient in the test group lay on the bed, a same person removed 5% of the Lavogula Lavender essential oil from a tube containing Lipogel with essential oil and then removed From precise measurement with the balance of a patient's legs from wrist to toe point to two finger straps and a length of 5 cm measured by a ruler uniformly, top to bottom for 1 minute.

#### Category

Treatment - Drugs

### 2

#### Description

second Intervention group: After obtaining informed consent, during hemodialysis while the patient in the test group was lying on the bed, a same person after wearing two grams of Lavandula Angustifolia essential oil 5% from the tube containing lipogel with The essential oil is removed and after careful measurement with a balance on the back of the patient's legs from ankle to toe, point to two fingers and 5 cm in length, as measured by a ruler, from top to bottom for 1 minute. It takes 1minutes

#### Category

Placebo

### 3

#### Description

Control group: There is no intervention by the research team and routine care is provided

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mazandaran Heart Center

##### Full name of responsible person

Abulqasim Fallah

##### Street address

Army Boulevard, Mazandaran Heart Center

##### City

Sari

##### Province

Mazandaran

##### Postal code

۴۸۱۵۷۳۳۹۷۱

##### Phone

+98 11 3304 4000

#### Email

publicrel@mazums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Citizen Kidney Disease Center

##### Full name of responsible person

Musa Ismaili

##### Street address

Keshavarz Boulevard Citizen Dialysis Center

##### City

Sari

##### Province

Mazandaran

##### Postal code

۴۸۱۵۷۳۳۹۷۱

##### Phone

+98 11 3304 4000

##### Email

publicrel@mazums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Hedayat Jafari

##### Street address

Sari, Imam Sq, Joybar 3way, Start of valiye asr highway, Mazandaran University of Medical Sciences

##### City

Sari

##### Province

Mazandaran

##### Postal code

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##### Phone

+98 11 3304 4000

##### Email

hedayat2003@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Sari University of Medical Sciences

#### Proportion provided by this source

100

#### 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

+98 11 3304 4000

**Email**

hedayat2003@yahoo.com

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Hedayat Jafari

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

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hedayat2003@yahoo.com

**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**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

Undecided - It is not yet known if there will be 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**

Not applicable