

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 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 Vafaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3324 3564

Email address

saravafaei.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

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Sari

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Phone

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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

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Sari

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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

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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

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Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

Nursery

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Email

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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

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