Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Angustifulia 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 Vafaee
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 11 3324 3564
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saravafaee.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 AABBCC, 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 Angustifulia 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
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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
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Postal code
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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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Phone
+98 11 3304 4000
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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

Person responsible for general inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Hedayat Jafari

Position
Associate prifessor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Nursery

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Person responsible for updating data

Contact

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Full name of responsible person
Hedayat Jafari

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Email
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