Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness and ineffectiveness of Rose esence on the sleep quality of hemodialysis patients

Protocol summary

Summary

This study will be done with aim to investigate the effect of Rose esence on the sleep quality of hemodialysis patients in Imam Reza hospital of Kermanshah in 2015. This study is a nonblinded clinical trial. The study population includes undergoing hemodialysis patients that refer to Imam Reza hospital of Kermanshah city. Before starting the study, the patients will receive Pittsburgh Sleep Quality questionnaire and a total of 32(study will done in phase 2) will selected and randomly will be assigned in two exprimental and control groups (16 members).Experimental group will use 3 drops of Rose esence 10%, every night before bed for a month. Patients and attendants will trained, while using spills 3 drops of Rose esence on a cotton ball into a layer of fabric that had already been prepared and will put them, and by a small pin install on the collar and breathing during the night and the morning after awakening separate from collar. In the control group will used sesame oil as a placebo. After the last day of the intervention, when they referring to the ward for hemodialysis, both groups will receive the final questionnaire and sleep quality will compared in the two groups. Inclusion criteria: Patient informed consent; History of dialysis at least 6 months at a rate of 1 to 7 times a week. Exclusion criteria: A score less than 5 of Pittsburgh Sleep Quality scale; Failure to perform systematic interventions for one third of intended time

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110214333N45**
Registration date: **2016-02-15, 1394/11/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-15, 1394/11/26

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-01-20, 1394/10/30

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness and ineffectiveness of Rose esence on the sleep quality of hemodialysis patients

Public title

Investigate the effect of Rose esence on the sleep quality of hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Age between 15 to 70 years; Patient informed consent; Patients undergoing hemodialysis; At least 6 months history of dialysis at a rate of 1 to7 times a week; Lack of Allergic Diseases Exclusion criteria: A score less than 5 of Pittsburgh Sleep Quality scale; Failure to perform systematic interventions for one third of intended time.

Age
From **15 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomly by tossing coin

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City
Kermanshah

Postal code

Approval date
2015-10-20, 1394/07/28

Ethics committee reference number
kums.rec.1394.123

Health conditions studied

1

Description of health condition studied
hemodialysis

ICD-10 code
Z49.1

ICD-10 code description
Extracorporeal dialysis

Primary outcomes

1

Description
Subjective sleep quality

Timepoint
Base line and end of the study (one month after the beginning of the study)

Method of measurement
By Pittsburgh Sleep Quality questionnaire

2

Description
Sleep latency

Timepoint
Base line and end of the study (one month after the beginning of the study)

Method of measurement
By Pittsburgh Sleep Quality questionnaire(PSQI)

3

Description
Duration of sleep

Timepoint
Base line and end of the study (one month after the beginning of the study)

Method of measurement
By Pittsburgh Sleep Quality questionnaire(PSQI)

4

Description
Sufficient sleep

Timepoint
Base line and end of the study (one month after the beginning of the study)

Method of measurement
By Pittsburgh Sleep Quality questionnaire(PSQI)

5

Description
Sleep disturbances

Timepoint
Base line and end of the study (one month after the beginning of the study)

Method of measurement
By Pittsburgh Sleep Quality questionnaire(PSQI)

Secondary outcomes

empty

Intervention groups

1

Description
Experimental group will use 3 drops of Rose esence 10%, every night before bed for a month. Patients and attendants will trained, while using spills 3 drops of Rose esence on a cotton ball into a layer of fabric that had already been prepared and will put them, and by a small pin install on the collar and breathing during the night and the morning after awakening separate from collar.
Category
Treatment - Drugs

2

Description
In the control group will used sesame oil as a placebo.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Touraj Mohamadyari
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences
Full name of responsible person
Koroush Hamzehee
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
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, Kermanshah 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Fatemeh Hadadian
Position
Master of Science in Medical Surgical Nursing
Other areas of specialty/work
Street address
School of Nursing & Midwifery, First of Dolatabad Boulvard,Eisar Square
City
Kermanshah
Postal code
Phone
+98 83 3828 0642
Fax
Email
- daneshjoo.610@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