Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison effect aromatherapy Chamomile and Damask rose essential oil with Alprazolam on sleep quality of hemodialysis patient

Protocol summary

Study aim
Comparison of the effect of Chamomile, Rosa damascena and Alperazolam on the quality of sleep in patients with hemodialysis

Design
The clinical trial has 3 intervention groups, with parallel groups, randomized.

Settings and conduct
The study is a clinical trial study of 3 groups of 90 patients undergoing hemodialysis.

Participants/Inclusion and exclusion criteria
Entry Criterion: 1- Having at least 30 years and maximum 70 years of age 2- Awarded for participation in the study 3- A record of at least 6 months of hemodialysis 4. Performing hemodialysis at least twice a week and at least 3 hours 5- Awareness , Not having noticeable speech and speech disorder 6-No history of allergic rhinitis, eczema or known respiratory problems, such as asthma and lack of olfactory disorder 7-No known psychological illness and no drug addiction as 8-Not susceptible to Chamomile essential oil and flowers of Mohammadi9- Absence of acute illness 10- No admission to hospital and surgery Exit criteria: 1. Non-collaboration during study 2. patient death 4. Renal transplantation

Intervention groups
Participants in two groups of Chamomile and Rose damascns each night and for seven nights, before going to bed, three drops of essential oil were poured on a cotton ball and put in a pre-prepared patch and put on the patient's clothes Snuggles, sniffs.In the third group, for seven nights, the alprazolam tablet is 0.5 before bedtime.

Main outcome variables
sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190521043663N1**
Registration date: **2019-06-20, 1398/03/30**
Registration timing: **prospective**

Last update: **2019-06-20, 1398/03/30**
Update count: **0**

Registration date
2019-06-20, 1398/03/30

Registrant information

Name
Fatemeh Samiei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2019-07-23, 1398/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison effect aromatherapy Chamomile and Damask rose essential oil with Alprazolam on sleep quality of hemodialysis patient

Public title
The effect of aromatherapy on sleep
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patient be Agree to participate in the study Patient have at least 6 months of hemodialysis Patient have a hemodialysis at least twice a week, and minimum 3 hours each time Patient have complete consciousness Patient do not have well known auditory and speech disorder Patient have no history of allergic rhinitis, eczema or known respiratory problems such as asthma and the absence of olfactory disorder Patient do not have known mental disease Patient not be addicted to drug
Exclusion criteria:
The test of the quality of sleep score base on using the Modified Pittsburgh Sleep Quality Index (PSQI) should be <5
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not 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 Birjand University of Medical Sciences
Street address
Birjand University of Medical Sciences , Ghafari Street, Birjand, Southern Khorasan, Iran.
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Approval date
2019-05-04, 1398/02/14
Ethics committee reference number
IR. BUMS.REC.1398.027

Health conditions studied

1

Description of health condition studied
Hemodialysis
ICD-10 code
Z49.31
ICD-10 code description
Encounter for adequacy testing for hemodialysis

Primary outcomes

1

Description
sleep quality
Timepoint
1-Before the intervention ,2- The seventh night after the intervention
Method of measurement
Pittsburg Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: In this group, each night from 10 pm to 6 am for seven nights, before the patient goes to bed, three drops of essential oil rose damascene flower with a droplet on a cotton ball inside a patch already made Prepare it and put it on its clothes and smell it at bedtime. Group 2: This group every night from 10 pm to 6 am for seven nights before the patient goes to bed, three drops of essential oil Put Mohammad a dropper on a cotton ball in a pre-prepared patch and attach it to his clothes and at bedtime. Group 3: For seven nights, Alperazol tablets M 0.5 is consumed as directed by the physician.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
A comprehensive treatment center for specific patients
Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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
Birjand University of Medical Sciences
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Person responsible for updating data

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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
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available