

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison the effect of aroma Inhalation of Orange and Levander Essence on fatigue and quality of Sleep in hemodialysis patients

Protocol summary

Summary

A clinical trial (cross-over) study was performed. After obtaining the written ethical permission from the Ethics Committee of Zabol University of Medical Sciences, the study was performed on patients undergoing Hemodialysis in Hemodialysis ward, Zabol Imam Khomeini hospital. Based on the inclusion criteria, the samples were randomized in two groups (A and B). The group A inhaled lavender extract first, then they received orange extract. The group B inhaled orange extract first, then they received orange extract. Each session was two weeks. There was also a two washout period between sessions. In the first stage of intervention all patients trained how to use the orange and lavender extracts. The night after hemodialysis, a drop of lavender or orange extract was poured onto a 2 x 2 cm gauze and trained to attach it on their shirt by a paper clip. The procedure was repeated three times a week. The level of fatigue and sleep quality was measured at the end of each week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060222772N1**

Registration date: **2016-06-17, 1395/03/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-17, 1395/03/28

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Zabol University of Medical Sciences

Expected recruitment start date

2016-03-10, 1394/12/20

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of aroma Inhalation of Orange and Levander Essence on fatigue and quality of Sleep in hemodialysis patients

Public title

Effect aromatherapy on fatigue and quality of Sleep in hemodialysis patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Hemodialysis three times a week; having a history of Hemodialysis treatments more than six months; informed consent for the study; lack of acute stressful event in the past 6 months (Death of loved ones); lack of history of allergy to aromas; lack of proven problem in sense of smell (healthy olfactory sense that was evaluated by a physician). Exclusion criteria:

unwillingness to participate in the trial; kidney transplantation; hospitalization in another ward except Hemodialysis ward for other reason (MI, CVC and dyspnea).

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Zabol University of Medical Science

Street address

Shahid Rajae st-Research and technology Deputy of
Zabol University of Medical science

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Postal code

9861663335

Approval date

2016-03-09, 1394/12/19

Ethics committee reference number

Zbmu.1.Rec.1394.132

Health conditions studied**1****Description of health condition studied**

End Stage Renal Disease

ICD-10 code

N18.5 Chro

ICD-10 code description

Chronic uraemia End stage kidney disease

Primary outcomes**1****Description**

Fatigue

Timepoint

Before and end of first and second weeks in first stage of intervention stage and end of third and fourth Weeks in two stage of intervention

Method of measurement

multidimensional fatigue inventory (MFI-20)

Secondary outcomes**1****Description**

Quality of Sleep

Timepoint

Before and end of first and second weeks in first stage of intervention stage and end of third and fourth Weeks in two stage of intervention

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

Intervention groups**1****Description**

In the first stage of intervention for study of Lavender effect on fatigue and sleep quality , patients were trained in order to The night after hemodialysis, one drop lavender or orange extract was poured onto a 2 x 2 cm gauze and attached to the patient`s shirt by special pins. Then the patients began to rest. This was repeated three times a week. It was, however, done every day during the second week. Patients also received their normal care. The level of fatigue and sleep quality was studied at the end of each week by related questionnaire.

Category

Other

2**Description**

In the second stage,for study effect of Orange on fatigue and quality of sleep , groups were exchanged to study the intervention of orange extracts. Group 1 received lavender extract, while group 2 received orange extract. Fatigue and sleep quality were studied at the end of each week.

Category

Other

Recruitment centers**1****Recruitment center**

Name of recruitment center
Dialysis Center of Imam Khomeini Hospital
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
Zabol University of Medical Science
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

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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