

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Comparison of the effect of aromatherapy with orange essential oils on anxiety of patients undergoing hemodialysis

Protocol summary

Summary

The aim of this research is Comparison the effect of orange essential oils aromatherapy on anxiety of hemodialysis patients. subjects had dialysis three times a week and lack of stressful events during the past 6 months This clinical trial study was accomplished on two groups, so that, 62 hemodialysis patients were randomly in two groups (orange oil, usual care). In the orange oil group, subjects inhaled orange oil by handkerchiefs smeared with one drop orange oil for 15-20 minutes. This method was used three times a week during four weeks. In the usual caring group, the cares that was routine in the hemodialysis ward was done for the subjects. The subjects level of anxiety in two groups was measured and compared before intervention, after first, second, third and fourth weeks of intervention, by Spielberg State-Trait Anxiety Inventory questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112318558N1**

Registration date: **2012-04-06, 1391/01/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-04-06, 1391/01/18

Registrant information

Name

Masomeh Kanani khisi

Name of organization / entity

Mashad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1853 9775

Email address

kananim2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashad University of Medical Sciences

Expected recruitment start date

2008-11-21, 1387/09/01

Expected recruitment end date

2009-03-05, 1387/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the effect of aromatherapy with orange essential oils on anxiety of patients undergoing hemodialysis

Public title

The Comparison of the effect orange essential oils on anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: dialysis three times a week; At least 6 months of hemodialysis; lack of stressful events during the past 6 months; lack of sedative drugs or other therapeutic measures (such as the use of vegetable oils, regular exercise) to reduce anxiety before six weeks; no use drug; no history of allergic rhinitis; or respiratory problems and no history of hospitalization or treatment because of other psychiatric disorders Exclusion criteria: Ashpylberger Anxiety Scale scores were obtained from more than 64 in state anxiety and more than 63 in

trait anxiety

Age
From **16 years** old to **86 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashad University of Medical Sciences

Street address
Mashad University of Medical Sciences, Daneshgah Street

City
Mashad

Postal code

Approval date
2008-09-27, 1387/07/06

Ethics committee reference number
951

Health conditions studied

1

Description of health condition studied
Anxiety of hemodialysis

ICD-10 code
F40-F48

ICD-10 code description
Neurotic, stress-related and somatoform disorders

Primary outcomes

1

Description

Anxiety

Timepoint
before intervention, after first, second, third and fourth weeks of intervention

Method of measurement
Spielberg State-Trait Anxiety Inventory questionnaire.

Secondary outcomes

1

Description
side complication and satisfaction

Timepoint
after intervention

Method of measurement
questionnaire.

Intervention groups

1

Description
In the orange oil group, subjects inhaled orange oil by smeared handkerchiefs with one drop of orange oil for 15-20 minutes. This method was used three times a week during four weeks. The Essential oils produced from the company of Gorgan. This essential oils was analyzed in the laboratory of company by Gas - Chromatography connected to mass spectrometer to ensure purity of essential oils and determine its exact composition. The analysis showed that the major compounds include: Limonene (%96.5), Betapynen (%0.37), ALfapynen (%0.3), Myrcen (%0.02). In the usual caring group, the cares that was routine in the hemodialysis ward was done for the subjects

Category
Treatment - Other

2

Description
The Essential oils produced from the company of Gorgan. This essential oils was analyzed in the laboratory of company by Gas - Chromatography connected to mass spectrometer to ensure purity of essential oils and determine its exact composition. The analysis showed that the major compounds include: Limonene (%96.5), Betapynen (%0.37), ALfapynen (%0.3), Myrcen (%0.02).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
hemodialysis ward of IMAM REZA hospital

Full name of responsible person
Kanani Khisi Masomeh

Street address

IMAM REZA hospital, Abnsina Street

City
mashad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashad University of Medical Sciences

Full name of responsible person

Afzal Aghaei

Street address

Mashad University of Medical Sciences, Daneshgah
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City

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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

Mashad 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

Name of organization / entity

Mashad University of Medical Sciences

Full name of responsible person

Masomeh Kanani Khisi

Position

Master Of Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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