Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Inhalation Therapy of Lavender on the severity and times Headaches of Patients During Hemodialysis

Protocol summary

Study aim

This clinical trial study was conducted to evaluate the effect of inhaled aromatherapy on lavender severity and frequency of headache during hemodialysis. In this regard, 82 patients were randomly selected from hemodialysis patients who had frequent headache during hemodialysis and were divided into intervention and control groups. The intervention group received lavender extract and the control group received distilled water. Aromatherapy begins after the headache begins during hemodialysis. The severity of headache was measured using visual analogue scale of pain severity, before aromatherapy, 30 minutes and one hour after aromatherapy. Intervention was performed for 4 weeks and data were finally analyzed.

Design

82 patients were randomly divided into intervention and control groups.

Settings and conduct

This study in the hemodialysis section can perform on physicians who have recurrent hemodialysis.

Participants/Inclusion and exclusion criteria

Entry requirements • Patients 18 years or older • Voluntary participation in the study • Having three hemodialysis sessions per week • No use of perfume and cologne before and during the intervention • No use of pain medication for 6 hours before intervention • No respiratory disease • No problem with the smell • No sensitivity to aromatherapy • No drug use • Earn a score equal to or above 3 on the numeric pain scale. • Having a history of recurrent hemodialysis headache Exclusion criteria: The patient withholds co-operation. • Problems or illnesses occur during the execution of the plan that prevent the patient from continuing to cooperate.

Intervention groups

People with frequent headaches during hemodialysis.

Main outcome variables

The effect of lavender essential oil inhalation on pain intensity has been investigated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190718044263N1**
Registration date: **2019-08-18, 1398/05/27**
Registration timing: **retrospective**

Last update: **2019-08-18, 1398/05/27**
Update count: **0**

Registration date

2019-08-18, 1398/05/27

Registrant information

Name

zeinab Jamshidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 5287 5898

Email address

jamshidi.z@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

2019-06-22, 1398/04/01

Actual recruitment end date

2019-07-21, 1398/04/30

Trial completion date

2019-07-21, 1398/04/30

Scientific title

The Effect of Inhalation Therapy of Lavender on the severity and times Headaches of Patients During Hemodialysis

Public title
The Effect of Inhalation Therapy of Lavender on the severity and times Headaches of Patients During Hemodialysis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients 18 years or older Voluntary participation in the study Having three hemodialysis sessions per week No use of perfume and cologne before and during the intervention • No use of pain medication for 6 hours before intervention No respiratory disease No problem with the smell No sensitivity to aromatherapy No drug use Earn a score equal to or above 3 on the numeric pain scale. Having a history of recurrent hemodialysis headaches
Exclusion criteria:
The patient withholds co-operation. • Problems or illnesses occur during the execution of the plan that prevent the patient from continuing to cooperate
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **82**
Actual sample size reached: **82**
Randomization (investigator's opinion)
Randomized
Randomization description
The research sample based on statistical formula consisted of 82 patients who were selected based on inclusion criteria and then They were randomly assigned to intervention and control groups (41 patients in each group) using randomized block design with block size 6 (using table of random permutations). The randomization list is compiled by a statistics expert. In this study, due to the nature of interventions, there is no blinding condition for patients and researchers.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Jundishapur University of Medical Sciences
Street address
Golestan
City
Ahwaz
Province
Khouzestan
Postal code
6135539345
Approval date
2019-05-04, 1398/02/14
Ethics committee reference number
IR.AJUMS.REC.1398.117

Health conditions studied

1

Description of health condition studied
headache
ICD-10 code
G44
ICD-10 code description
Other headache syndromes

Primary outcomes

1

Description
Headache
Timepoint
Before the intervention, 30 minutes and one hour after the intervention
Method of measurement
Visual scale measuring pain intensity

Secondary outcomes

1

Description
Frequency of headache
Timepoint
At the end of the intervention
Method of measurement
Count the number of headaches

Intervention groups

1

Description
Intervention group: Inhalation aromatherapy was

performed with 2% lavender extract. 3 drops of lavender essential oil is poured onto a cotton pad and the patient inhales for 30 minutes after the headache begins.

Category

Treatment - Drugs

2

Description

Control group: This group uses three drops of distilled water as the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dialysis Ward of Golestan Hospital in Ahwaz and Dialysis ward of Shahid Zadeh Behbahan Hospital

Full name of responsible person

Fatemeh Shokripoor

Street address

Golestan

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Ahwaz and Behbahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Iraj Nazary

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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

Ahvaz 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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Zeinab Jamshidi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Zeinab Jamshidi
Position
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Latest degree
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Other areas of specialty/work
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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
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
Undecided - It is not yet known if there will be a plan to make this available