Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Affection of Aromatherapy on Neuropathic Pain and Quality of Life in Diabetic Patients Referring to Diabets Clinics Affiliated to Shiraz University of Medical Science,2019-2020

Protocol summary

Study aim

Determination the affection of aromatherapy on neuropathic pain and quality of life in diabetic patients referring to diabetes clinics affiliated to Shiraz university of medical science,2019to20201)Determination and comparison of mean pain score of neuropathy in aromatherapy, placebo and control group before and after the intervention2)Determination and comparison of mean score of quality of life in diabetic patients in aromatherapy, placebo and control group before and after the intervention3)Comparison of mean score of quality of life in diabetic patients between aromatherapy, placebo and control groups before and after the intervention4)Comparison of mean pain score arising from neuropathy between the three groups of aromatherapy, placebo and control before and after the intervention.

Design

Clinical trial with control group, intervention 1 and 2, sample size 75, randomized triple blind

Settings and conduct

Shiraz Diabetes Clinics,Neuropathy ,Intervention group 1: Apply lavender oil to the knee area (2.5cm per foot) each night before bedtime for one month,In the second group, placebo is usedThe control group received no intervention.

Participants/Inclusion and exclusion criteria

Diabetic Patients,18 to 65 years,Willingness to participate,Obtain a score higher than or equal to 4 on the DN4 questionnaire,Lack of other diseases causing neuropathic pain (trauma, systemic diseases etc.),Not having any scars on the legs,No sensitivity to essential oils,Not catching up coagulation disorders,No pregnancy

Intervention groups

The effect of aromatherapy by skin absorption of lavender oil on neuropathy of diabetic patients with lower knee (2.5cm per leg) but in the second intervention group placebo is used.

Main outcome variables

Greater than or equal to 4 on the DN4 questionnaire;Pain Score in Pain Evaluation Criteria (VAS);Received score from Persian Quality of Life Questionnaire 36 Questions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191106045352N1**
Registration date: **2020-07-10, 1399/04/20**
Registration timing: **retrospective**

Last update: **2020-07-10, 1399/04/20**
Update count: **0**

Registration date

2020-07-10, 1399/04/20

Registrant information

Name

Monireh Rahpeima

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5800 9341

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Affection of Aromatherapy on Neuropathic Pain and Quality of Life in Diabetic Patients Referring to Diabets Clinics Affiliated to Shiraz University of Medical Science,2019-2020

Public title
"Effect of Aromatherapy on Neuropathic pain Arising from Diabet"
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diabetic Patients Ages 18 to 65 years Willingness to participate in research Obtain a score higher than or equal to 4 on the DN4 clinical acceptance questionnaire
Exclusion criteria:
Nonconformity the protocol Not willing to continue cooperation Existence of other diseases causing neuropathic pain (trauma, systemic diseases, autoimmune, etc.) having any scars on the legs catching up diabetic foot sensitivity to essential oils catching up coagulation disorders pregnancy
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
According to statistical counseling, 75 members were randomly assigned to simple members of the population using a random number table, and then these individuals were randomly assigned to five groups using statistical blocking software in three groups: control, intervention, and placement. Are given.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, participants are summoned separately with a schedule, and during informed consent, information is provided in a way that leads to bias. Three intervention groups are named A, B, and D, and the researcher and the person collecting the information are not aware of the naming process. The data analyst also analyzes the data presented in three groups, A, B, and D.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
71345-1978
Approval date
2019-10-09, 1398/07/17
Ethics committee reference number
IR.SUMS.REC.1398.897

Health conditions studied

1

Description of health condition studied
diabetic neuropathy
ICD-10 code
E09.40
ICD-10 code description
Drug or chemical induced diabetes mellitus with neurological complications with diabetic neuropathy, unspecified

Primary outcomes

1

Description
The percentage of people with greater than or equal to 4 on the DN4 clinical acceptance questionnaire.
Timepoint
Before the intervention, the second week, the fourth week
Method of measurement
DN4 clinical acceptance questionnaire

2

Description
Pain Score in Pain Evaluation Criteria (VAS)
Timepoint
Before the intervention, the second week, the fourth week
Method of measurement
Pain Assessment Criterion (VAS)

3

Description
Received score from Persian Quality of Life Questionnaire 36 Questions (Dr. Montazeri)
Timepoint
Before the intervention, the second week, the fourth week
Method of measurement
Farsi Quality of Life Questionnaire 36 questions(Dr.Montazeri)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: "First intervention group": Lavender oil (3%) produced in Noorhan company in the knee area down (2.5 cc for each leg) is applied every night before bed for a month.
Category
N/A

2

Description
Intervention group: "Second Intervention Group": Plasbo oil produced by Noorhan Company in the knee area is reduced (2.5 cc for each leg) every night before bed for a month.
Category
N/A

3

Description
Control group: This group does not receive any intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Qutbuddin Diabetes Clinic
Full name of responsible person
Monireh Rahpeima
Street address
Qutbuddin Diabetes Clinic, East Fakhrabad St, Kazerun Gate, Shiraz,Fars.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Roxana Johnghorban
Street address
Fatemeh School of Nursing and Midwifery, Namazi Hospital, Namazi Square, Shiraz
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janghorban@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Monireh Rahpeima
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
In this study, individual data are considered that can be shared after making people unrecognizable
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
In line with scientific research and with the approval of the faculty.
From where data/document is obtainable
Fatemeh School of Nursing and Midwifery, Namazi Hospital, Namazi Square, Shiraz 00987136474254
What processes are involved for a request to access data/document
Submitting a valid letter and approval from Fatemeh School of Nursing and Midwifery
Comments