

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The Affection of Aromatherapy on Neuropathic Pain and Quality of Life in Diabetic Patients Referring to Diabetics 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, 2019 to 2020 1) Determination and comparison of mean pain score of neuropathy in aromatherapy, placebo and control group before and after the intervention 2) Determination and comparison of mean score of quality of life in diabetic patients in aromatherapy, placebo and control group before and after the intervention 3) Comparison of mean score of quality of life in diabetic patients between aromatherapy, placebo and control groups before and after the intervention 4) 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 used The 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

Email address

m-rahpeima@sums.ac.ir

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 Diabetics 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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Province

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5473371638

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m.rahpeima191372@gmail.com

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

City

Shiraz

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Postal code

7193613119

Phone

+98 71 3647 4254

Email

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

Street address

No.938,9/1 Mohtasham Street,Azadeghan Ave,1Th Phase,Sadra Town

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7199349380

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Position

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Latest degree

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mojgan Rivaz

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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7193613119

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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Monireh Rahpeima

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