

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of inhalation aromatherapy with lavender essential oil on anxiety before dental procedures

Protocol summary

Study aim

Determining the effect of inhaled aromatherapy with lavender essential oil on patients' anxiety before dental procedures

Design

The present study performed clinical trials with intervention and control groups with parallel, double-blind, and randomized groups on 64 patients

Settings and conduct

The present study is performed on patients under dental procedures in Larestan dental clinics

Participants/Inclusion and exclusion criteria

entry criteria:age over 18 years,Getting a score of over 20 using the spielberger questionnaire and Exit criteria:lung problems,history of allergy to herbal medicines,olfactory disturbance, history of seizure or epilepsy,taking anti- anxiety medications(Banzodiazepines)72 hours before dental procedures

Intervention groups

In the intervention group, 2 drops of lavender essential oil, 2% are poured on the handkerchief by a dropper and the patient inhales it for 20 minutes. In the placebo group (control), 2 drops of distilled water are poured on the handkerchief by a dropper and the patients inhale the placebo for 20 minutes.

Main outcome variables

Anxiety Scale Questionnaire and Vital signs Checklist

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200521047534N1**

Registration date: **2020-11-10, 1399/08/20**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-10, 1399/08/20**

Update count: **0**

Registration date

2020-11-10, 1399/08/20

Registrant information

Name

Zahra Seifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5224 5009

Email address

z.seifi2010@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-21, 1399/07/30

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of inhalation aromatherapy with lavender essential oil on anxiety before dental procedures

Public title

Effect of lavender on anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

age over 18 years Getting a score of over 20 using the

spielberger questionnaire

Exclusion criteria:
 lung problems history of allergy to herbal medicines
 olfactory disturbance a history of seizure or epilepsy
 taking anti-anxiety medications (Benzodiazepines) 72
 hours before dental procedures

Age
 From **18 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
 Target sample size: **64**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Block Randomization is used to balance the number of samples allocated to each study group. According to the volume of the final sample in this study, 8 blocks of 8 are used to allocate participants in each group and the allocation of intervention and control group to letters A and B will be done randomly according to the pre-determined blocks. Individuals are divided into two groups according to the criteria for entering and leaving the study and according to randomly designed blocks (in each block, 4 individuals for the intervention group and 4 individuals for the control group)

Blinding (investigator's opinion)
 Double blinded

Blinding description
 Due to the fact that anxiety is measured subjectively and can be influenced by induction or indoctrination, anxiety measurement will be done in two ways. After designing the random allocation, the lead researcher provides it to the researcher and asks him or her to divide the individuals into two groups according to the random sequence of blocks. At this stage, the patient and the researcher will not be aware of the type of individual group (intervention or placebo) and the type of treatment assigned. For this purpose, prescribing treatment and research will be two separate individuals.

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Larestan University of Medical Sciences

Street address

Research Assistant of Larestan University of Medical Science, Karmandan Ave, North Gadir Boulevard, New City

City

Larestan

Province

Fars

Postal code

74318-89629

Approval date

2020-05-18, 1399/02/29

Ethics committee reference number

IR.LARUMS.REC.1398.005

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Anxiety score in Spielberger questionnaire

Timepoint

before and after intervention

Method of measurement

Anxiety Spielberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 2 drops of lavender essential oil, 2% are poured on the handkerchief by a dropper and the patient inhales it for 20 minutes.

Category

Treatment - Other

2

Description

Control group: 2 drops of distilled water are poured on

the handkerchief by a dropper and the patients inhale the placebo for 20 minute

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehr Dental Clinic

Full name of responsible person

Zahra Seifi

Street address

Mehr clinic, Helal Ahmar Ave, New City, Lar, Fars Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Larestan University of Medical Sciences

Full name of responsible person

Dr zahra keshtkaran

Street address

Research Assistant of Larestan University of Medical Science, Karmandan Ave, North Gadir Boulevard, New City, Larestan, Fars

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Larestan 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

Larestan University of Medical Sciences

Full name of responsible person

Zahra Seifi

Position

Faculty member

Latest degree

Master

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

It can be shared by unidentifiable participants

When the data will become available and for how long

Access begins a year after the publication of results

To whom data/document is available

People who are working in the academic and scientific institutions

Under which criteria data/document could be used

It needs the agreement of Larestan Medical School

From where data/document is obtainable

zahra seifi, faculty member of larestan medical school,
z.seifi2010@yahoo.com, tell phone:07152255278, cell
phon number:09177827970

What processes are involved for a request to access data/document

Written and formal request to the vice chancellor for
research of Larestan University of Medical Sciences

Comments