Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the effect of lavender (Lavandula angustifolia) oral drops in changing dental anxiety score in patients referred for endodontic treatment

Protocol summary

Study aim

The effect of oral lavender drops on reducing anxiety in patients referred for endodontic treatment

Design

A clinical trial with a control group with parallel double-blind groups on 64 patients. A table of random numbers was used for randomization.

Settings and conduct

If the patient is accidentally placed in the intervention group, he will receive a disposable plastic cup with a lid, the contents of which are not visible, containing 20 oral drops of lavender extract in 250 ml of water. Patients who are randomly assigned to the control group receive a disposable plastic cup with a lid of the same shape, size, and color that contains 20 drops of water poured into 250 ml of water. Due to the fact that lavender extract has a special smell and aroma, in both groups, we cover the plastic cup lid with lavender extract. After 60 minutes of drinking the solutions, the anxiety questionnaire is completed again by the participants of the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients who need endodontic treatment; Exclusion criteria: 1. Age under 12 years. 2. Not have a healthy mental state. 3. Has used anti-anxiety medications such as benzodiazepines in the past week. 4. A woman who is pregnant. 5. A breastfeeding woman 6. Have a history of contact dermatitis symptoms after consuming lavender essential oil. 7. Have a history of allergies to the main components of lavender extract, including linalool. 8. Patients who are taking coumarin.

Intervention groups

The study includes two groups of intervention and control. The intervention group receives the main medicine, which is lavender extract. The control group receives water in a glass with same shape and size.

Main outcome variables

Patients' anxiety scores are measured by a modified dental anxiety questionnaire before and after taking medication or placebo.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120908010773N2**
Registration date: **2021-09-12, 1400/06/21**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-12, 1400/06/21**
Update count: **0**

Registration date

2021-09-12, 1400/06/21

Registrant information

Name

Hamid Razavian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-11, 1400/06/20

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of lavender (Lavandula angustifolia) oral drops in changing dental anxiety score in patients referred for endodontic treatment

Public title

The effect of lavender oral drops in anxiety in patients referred for endodontic treatment

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients referred for endodontic treatment

Exclusion criteria:

Mental problems Inability to complete the questionnaire Taking anti-anxiety medications over the past week Pregnant women Breastfeeding women The patient has a history of allergies after consuming lavender Patient taking coumarin

Age

From **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method using a table of random numbers is used. In this study, which includes 64 samples, the numbers 00 to 64 are assigned to the samples. Then we randomly select a table point in the row direction. We select numbers smaller than the size of the study population. The selected numbers are in fact the individual code of the community that is selected as the sample. We will continue this until the sample size is complete and reaches the number 64.

Blinding (investigator's opinion)

Double blinded

Blinding description

Study participants are not aware of the contents of the glass and whether it was a medicine or a placebo. Before the clinical caregiver gives the medication and placebo to the participants, another person performs the steps of pouring the drug and the placebo into the glass, and in this way, the clinical caregiver is blinded. Also, the main researcher of the project has no information about contents of each glass and does not know anything about which group receive placebo and which group receive medicine.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan university of medical science, Hezar jerib Ave

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2021-03-17, 1399/12/27

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.837

Health conditions studied

1

Description of health condition studied

Dental anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Dental anxiety score in modified dental anxiety survey

Timepoint

Measure anxiety at the beginning of the study and one hour after consuming lavender

Method of measurement

Modified dental anxiety scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One use of 20 drops of oral lavender extract in 250 ml of water

Category

Treatment - Drugs

2

Description

Control group: One use of 20 drops of water poured into a glass containing 250 ml of water.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan faculty of dentistry

Full name of responsible person
Seyed Hamid Razavian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shaghayegh Haghjoo Javanmard

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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

Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Seyed Hamid Razavian

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

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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

Only part of the data, such as the original outcome information, can be shared

When the data will become available and for how long

The access period will be one year after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Can be used in similar clinical designs

From where data/document is obtainable

Dr. Seyed Hamid Razavian Isfahan School of Dentistry Sofeh St. Contact number 09133314371

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

A full explanation of the reason for the documents and the contact address must be provided so that it can be sent to the documents within 1 month.

Comments