

# 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)

##### Phone

+98 31 1624 3998

##### Email address

razavian@dnt.mui.ac.ir

##### 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**  
Isfahan  
**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

**Street address**

Soffeh Blv

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3303 3950

**Email**

razavian@dnt.mui.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjoo Javanmard

**Street address**

Hezar jerib Ave

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 8138

**Email**

sh\_haghjoo@med.mui.ac.ir

**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**

Dentistry

**Street address**

Soffeh Blv

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3669 2588

**Email**

razavian@dnt.mui.ac.ir

**Person responsible for scientific 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**

Dentistry

**Street address**

Soffeh Blv

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3669 2588

**Email**

razavian@dnt.mui.ac.ir

## Person responsible for updating data

### 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**

Dentistry

**Street address**

Soffeh Blv

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3669 2588

**Email**

razavian@dnt.mui.ac.ir

## 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**