

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The effect of lavender inhalation on the pain perception of separator placement in patients needing orthodontic treatment: A randomized clinical trial

Protocol summary

Study aim

Determine the effect of lavender on orthodontic pain

Design

Clinical trial with control group, Block randomization

Settings and conduct

People referring to the orthodontic department of Shiraz Dental School are selected and if they sign the consent form, they can enter the study. The study is: before placing the separator, they inhale the herb given to them. Before and after placing the separator, they record the amount of pain in the VAS questionnaire. Then, at home, they report re-inhalation and pain at the mentioned times. Then a study is performed on the amount of pain reported between control and placebo group. Participants, main researcher, effect Assessor, analyzer are all blind. The secretary assigns a label to each of the herbs: A and B. These substances are in the black bottle and only the secretary knows which label belongs to which herb.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Need separator placement to begin fixed orthodontic treatment in the maxillary and mandibular arch 2. Aged between 14 and 19 3. Patients who are informed and sign the written informed consent 4. Who does not use antibiotics, analgesics, anti-inflammatory, anti-coagulant, diuretics, oral anti-diabetics, lithium, cyclosporine, and methotrexate 5. Who has no need for antibiotic prophylaxis 6. Who has no chronic systemic disease Exclusion criteria: 1. A patient who uses analgesics 2. A patient who misses the session 3. Early loss of separators 4. A patient who wants to exit the survey

Intervention groups

Intervention group: The participants have to instill five drops of their respective medication on a gauze and hold it about 20 cm from their nose for 5-10 minutes and breathe normally just before separator insertion, 4, 8, 12,

24, 36 and 48 hours afterward.

Main outcome variables

The amount of pain according to visual analogue scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111130008257N3**

Registration date: **2020-08-02, 1399/05/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-02, 1399/05/12**

Update count: **0**

Registration date

2020-08-02, 1399/05/12

Registrant information

Name

Maryam Karandish

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3628 9913

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-25, 1399/05/04

Expected recruitment end date

2020-09-04, 1399/06/14

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of lavender inhalation on the pain perception of separator placement in patients needing orthodontic treatment: A randomized clinical trial

Public title
Effect of lavender inhalation on the pain perception of orthodontic separator placement

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Need separator placement to begin fixed orthodontic treatment in the maxillary and mandibular arch Aged between 14 and 19 Patients who are informed and sign the written informed consent Who does not use antibiotics, analgesics, anti-inflammatory, anti-coagulant, diuretics, oral anti diabetics, lithium, cyclosporine, and methotrexate Who has no need for antibiotic prophylaxis Who has no chronic systemic disease
Exclusion criteria:
A patient who uses analgesics A patient who misses the session Early loss of separators A patient who wants to exit the survey

Age
From **14 years** old to **19 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization method is used. The length of the block is 8 and the number of treatment is 2. The statistician will randomly set the arrangement of blocks by random allocation software 2.0 and assigns them to the number of people. 16 bottles of lavender and 16 bottles of sesame oil are filled and the secretary gives one label A and the other B. Then, according to the list participants' medication is given .

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participants, main researcher, effect Assessor, analyzer are all blind. The secretary assigns a label to each of the herbs: A and B. These substances are in the black bottle

and only the secretary knows to which herb it belongs. We ask the patient to inhale the herb not knowing what it is.

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

Dentistry School, Shiraz University of Medical Sciences, Mehr Ave, Qasrodasht Blvd

City

Shiraz

Province

Fars

Postal code

۷۵۱۷۸- ۷۱۹۵۶

Approval date

2020-06-21, 1399/04/01

Ethics committee reference number

IR.SUMS.DENTAL.REC.1399.068

Health conditions studied

1

Description of health condition studied

orthodontic separator placement

ICD-10 code

Z46.4

ICD-10 code description

Encounter for fitting and adjustment of orthodontic device

Primary outcomes

1

Description

The amount of pain regarding to visual analogue scale

Timepoint

Just before separator placement, immediately after separator placement, 3 h post-treatment, 12 h post-treatment, 24 h post-treatment , and 48 h after separator placement

Method of measurement

Visual analogue scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants have to instill five drops of lavender on a gauze and hold it about 20 cm from their nose for 5-10 minutes and breathe normally just before separator insertion, 4, 8, 12, 24, 36 and 48 hours afterward.

Category

Treatment - Drugs

2

Description

Control group: The participants have to instill five drops of sesame oil on a gauze and hold it about 20 cm from their nose for 5-10 minutes and breathe normally just before separator insertion, 4, 8, 12, 24, 36 and 48 hours afterward.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental school of Shiraz University of Medical Sciences

Full name of responsible person

Maryam Tazarvi Fard Shirazi

Street address

Dentistry School of Shiraz University of Medical Science, Mehr Ave, Ghasrodasht Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Azadeh Andisheh Tadbir

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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

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

Maryam Tazarvi Fard Shirazi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Karandish

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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/documentAge, Sex, The amount of pain according to visual
analogue scale, The area of separator insertion**When the data will become available and for how long**

Access period starts from 2021

To whom data/document is availableResearchers working in academic and scientific
institutions**Under which criteria data/document could be used**Provided that the personal information of the participants
is not disclosed and citing the relevant article is**From where data/document is obtainable**

Email: maryam_ta76@yahoo.com

What processes are involved for a request to access data/documentAfter introducing and ensuring the accuracy of the
person's information, the data will be sent to him/her
within a week.**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Tazarvi Fard Shirazi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street addressDentistry School of Shiraz University of Medical
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