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 mandiblular 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-coagulatant, 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)

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+98 71 3628 9913

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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 mandiblular 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-coagulatant, 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

۱۵۸۷۸- ۷۱۹۵۶

Approval date

2020-06-21, 1399/04/01

Ethics committee reference number

IR.SUMS.DENTAI.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
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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
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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

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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
Age, 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 available
Researchers 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/document
After introducing and ensuring the accuracy of the person's information, the data will be sent to him/her within a week.
Comments