

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Effect of Berberine mouthwash on pain caused by elastomeric Separator placement

Protocol summary

Study aim

Effect of Berberine mouthwash on pain caused by elastomeric Separator insertion

Design

This clinical trials study was conducted in parallel, randomized, and double blind groups of 60 patients. Study phase is 3 . Participants will be divided into two equal groups using random numbers: A (intervention group) and B (control group). In group A, patients will receive Berberine and will receive placebo in group B.

Settings and conduct

This study will be carried out at the dental faculty of Ahvaz University. The number of participants is 60. Patients and researcher do not know who in what group is . Mouthwashes will be provided in the same glasses by the Drug Center. To the intervention and control groups, Berberine and placebo will be given. Patients' pain is recorded using the VAS scale on days 2, 1, 5 and 7.

Participants/Inclusion and exclusion criteria

Entry Criteria: People aged between 18 and 35 years old, people with no specific systemic disease, people with no pain in other teeth or other parts of the oral cavity, selected teeth are vital without endodontic and periodontal problems, tight contact of the first permanent molar With adjacent teeth, the presence of teeth in front of the first permanent molar teeth in the opposite jaw, absence of space in the jaw. Exit criteria: use of any drug during the study, falling of separator, failure to complete the questionnaire, inappropriate use of mouthwash, history of allergy

Intervention groups

"Intervention group": The volunteers in this group will be given the Berberine mouthwash . "Control group":They will receive the Placebo.Participants in both groups should use mouthwashes for 3 days, 3 times a day, at 10 cc for 1 minute.

Main outcome variables

Pain scale based on Visual Analogue Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181115041667N1**

Registration date: **2019-06-08, 1398/03/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-08, 1398/03/18**

Update count: **0**

Registration date

2019-06-08, 1398/03/18

Registrant information

Name

Sayedeh Zeinab Eftekhari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8383

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eftekhari-z@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-04, 1398/03/14

Expected recruitment end date

2019-07-05, 1398/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Berberine mouthwash on pain caused by elastomeric Separator placement

Public title

Effect of Berberine mouthwash on pain caused by orthodontic treatments

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The samples are in the age range of 18-35, who can execute the study carefully and sign the consent form voluntarily The samples lack any specific systemic disease (such as gastrointestinal and coagulation diseases, etc.) The selected teeth are vital and have no endodontic problems The selected teeth have no periodontic problems The sample doesn't mention any pain in other teeth or other parts of the oral cavity The contact of the first permanent molar with its adjacent teeth is tight so that the banding of the first permanent molar in the beginning of the treatment requires two-way separating (is checked using dental floss) Lack of space in the desired jaw There is a tooth in front of first permanent molar in front jaw

Exclusion criteria:

Taking any medication during the study Separator loss Not completing the questionnaire Improper use of mouthwash History of allergy to Berberine Pregnancy or breastfeeding

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study the randomization will be done using random numbers table. After consultation with the statistics specialist even numbers will be considered for the intervention group and odd numbers for control group. The researcher stays on one of the numbers then the right direction which predefined to move and the numbers will be registered.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and researcher will not be aware of the type of herbal mouthwash. The first Berberine will be prepared in the Ahvaz Jundishapur University Of Medical Sciences. Then the phrmacist will place the Berberin and Placebo in the same glasses. Only the pharmacist will be aware of the type of content inside glasses

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz jundishapur University of Medical Sciences

Street address

Assistance of Research and Technology Development of Ahvaz Jundishapur University of Medical Sciences , Academic Town, Golestan St

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-06-02, 1397/03/12

Ethics committee reference number

IR.AJUMS.REC.1397.186

Health conditions studied**1****Description of health condition studied**

The pain caused by the separator placement

ICD-10 code

R52.1

ICD-10 code description

Chronic intractable pain

Primary outcomes**1****Description**

Pain scale based on Visual Analogue Scale

Timepoint

Immediately after separator placement, 2 hours later and 6 hours later on the first day, at 10 am and 6 am on the second and third days, at 10 am on the seventh day

Method of measurement

Description of the patient's pain based on the Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They must use the Berberine mouthwash(prepared in the Ahvaz Jundishapur University Of Medical Sciences) for 3 days, threewice a day, each time 10 CC for 1 minutes.

Category

Prevention

2

Description

Control group: They must use placebo for 3 days, threewice a day, each time 10 CC for 1 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Jundi Shapur University Of Medical Sciences
School Of Dental Medicine

Full name of responsible person

Dr Seyede Zeynab Eftekhari

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Jundi Shapur University Of Medical Sciences, Golestan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mohammad Badavi

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University of Ahvaz, Assistant Professor of Research
and Technology, University of Medical Sciences Ahvaz
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Web page address

<http://www.vchresearch.ajums.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Seyede Zeynab Eftekhari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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