

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Evaluation of the the efficacy of bromelain and turmeric on pain after orthodontic separator placement: A single center, triple blind, randomized clinical trial

#### Protocol summary

##### Study aim

Evaluating the effect of bromelain and bromelain plus turmeric in controlling the pain after orthodontic separator placement

##### Design

A single center, triple-blind, randomized, controlled trial to evaluation the effect of bromelain and bromelain plus turmeric in controlling the pain after orthodontic separator placement in 117patients.

##### Settings and conduct

117 Participants will be recruited from orthodontic patients attending the orthodontic clinic at the Dental faculty of Shiraz University of Medical Science. Block randomization method will be used with block length=9 to allocate patients to three study groups with a 1:1:1 ratio. Each patient will be asked to pick a tablet. All tablets will be covered by identical gelatin cover, so the investigators, the patients and the statistician will be all blind to the treatment groups. A visual analogue scale (VAS) will be used to determine the level of pain Immediately after separator placement (T0), 2 hours post treatment (T1), 6 hours post treatment (T2), 24 hours post treatment (T3), and 48 hours after separator placement (T4).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Need separator placement to begin orthodontic treatment in the maxillary arch; Not currently using antibiotics, analgesics, anti-inflammatory, anti-coagulative, diuretics, oral anti diabetics, lithium, cyclosporine and methotrexate; No need for antibiotic prophylaxis; Not pregnant or nursing  
Exclusion criteria: Extraction or missing of any maxillary teeth except from third molars; Reporting contraindication for NSAIDs, Bromelain and Turmeric; use of other analgesics during the period of the study

##### Intervention groups

Control group: 400 mg Ibuprofen Intervention group: 200

mg Bromelain Intervention group: 150 mg Bromelain + 300 mg Turmeric

##### Main outcome variables

Pain intensity after elastic separator placement in orthodontics treatment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181121041713N3**

Registration date: **2020-10-06, 1399/07/15**

Registration timing: **prospective**

Last update: **2020-10-06, 1399/07/15**

Update count: **0**

##### Registration date

2020-10-06, 1399/07/15

##### Registrant information

##### Name

neda babanouri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3628 0801

##### Email address

babanouri@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-20, 1399/08/30

##### Expected recruitment end date

2020-12-20, 1399/09/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the the efficacy of bromelain and turmeric on pain after orthodontic separator placement: A single center, triple blind, randomized clinical trial

**Public title**

Effect of Bromelain and Turmeric on orthodontic pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Need separator placement to begin orthodontic treatment in the maxillary arch Aged 15 years or older Not currently using antibiotics, analgesics, anti-inflammatory, anti-coagulative, diuretics, oral anti diabetics, lithium, cyclosporine and methotrexate No need for antibiotic prophylaxis Not pregnant or nursing

**Exclusion criteria:**

Extraction or missing of any maxillary teeth except from third molars Smoking Patients with chronic systemic diseases or clotting disorders Reporting contraindication for NSAIDs, Bromelain and Turmeric Reporting allergy to pineapple

**Age**

From **15 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **135**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization method will be used with block length = 9, using online software RANDOM.ORG to allocate patients to three experimental groups with a 1:1:1 ratio.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

In each groups all tablets will be covered by identical gelatin cover, so the investigators, the patients and the statistician will be all blind to the treatment groups.

**Placebo**

Not 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**

Qasrodashe Ave,Mehr Blvd

**City**

Shiraz

**Province**

Fars

**Postal code**

7195615878

**Approval date**

2020-06-21, 1399/04/01

**Ethics committee reference number**

IR.SUMS.DENTAL.REC.1399.067

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

Evaluation of pain intensity after separator placement in orthodontics patients.

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Evaluation of pain intensity after elastic-separators placement in orthodontic patients

**Timepoint**

2, 6, 24 and 48 hours after elastic-separators placement

**Method of measurement**

The Visual Analogue Scale (VAS) is used to determine the level of pain and discomfort.

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: 200 mg Bromelain

**Category**

Treatment - Drugs

## 2

### Description

Intervention group: 150 mg Bromelain + 300 mg Turmeric

### Category

Treatment - Drugs

## 3

### Description

Control group: 400 mg Ibuprofen

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shiraz School of Dentistry

##### Full name of responsible person

Neda Babanouri

##### Street address

Qasrdasht Street, Qom Abad Blvd.

##### City

Shiraz

##### Province

Fars

##### Postal code

7195615878

##### Phone

+98 71 3628 0801

##### Email

nedababanouri@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Assistant for Research and Technology

##### Street address

Qasrodasht Ave, Mehr Blvd

##### City

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7195615878

##### Phone

+98 71 3628 0801

##### Email

babanouri@sums.ac.ir

##### 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

Dr. Neda Babanouri

##### Position

Assistant Professor of Orthodontics, Shiraz Dental School

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

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Qasrodasht Ave, Mehr Blvd

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

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Dr. Neda Babanouri

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Dr. Neda Babanouri  
**Position**  
Assistant Professor of Orthodontics, Shiraz Dental  
School  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Qasrodasht Ave, Mehr Blvd  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

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

### 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