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.DENTAI.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
Shiraz
Province
Fars
Postal code
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
Street address
Qasrodasht Ave, Mehr Blvd
City
Shiraz
Province
Fars
Postal code
7195615878
Phone
+98 71 3628 0801
Email
babanouri@sums.ac.ir

Person responsible for scientific 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
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+98 71 3628 0801

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babanouri@sums.ac.ir

Person responsible for updating data

Contact

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Shiraz University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor of Orthodontics, Shiraz Dental School

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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