Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Bromelain on Pain, Swelling and Trismus after Surgery in Orthognathic Patients

Protocol summary

Study aim

The effect of bromelain on pain, swelling and trismus after surgery in orthognathic patients

Design

Clinical trial with a control group, with parallel groups, three blinded, randomized, phase 3 on 20 patients. For randomization, the computer software will be "Random Allocation Software".

Settings and conduct

therapeutic goal; in Mashhad Dental Faculty and Mother Hospital; Patients are divided into two groups of 10. After surgery, both groups of patients will be given 8 mg dexamethasone every 8 hours for three days, cefazolin 1 mg every 6 hours for three days, and Apotel every 6 hours for 3 days, in addition to the intervention group Bromelain 200 mg daily and placebo (capsules containing lactose) will be given to the control group in 3 meals for up to 8 days. Study variables including pain, trismus, swelling will be investigated at different times. Only the pharmacist knows the type of pills (placebo/bromelain) based on coding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of the Disease by an Orthodontist and Surgery by a Maxillofacial Surgeon؛ Willingness to Cooperate؛ Not taking supplements for at least one month before. Exclusion criteria: Suffering from chronic diseases such as diabetes mellitus, kidney failure, liver disorder and cancer؛ Suffering from other autoimmune and inflammatory diseases؛ Suffering from hormonal disorders, thyroid disorders؛ Alcohol consumption and hookah use؛ Smoking and being exposed to secondhand smoke chronically؛ Unwillingness to participate in the study.

Intervention groups

Intervention group: consumption of 200 mg bromelain supplement capsule powder three times a day for 8 days
Control group: consumption of powder inside the placebo capsule three times a day for 8 days

Main outcome variables

Evaluation of swelling, pain and mouth opening before and after the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230517058214N1**
Registration date: **2023-06-19, 1402/03/29**
Registration timing: **prospective**

Last update: **2023-06-19, 1402/03/29**
Update count: **0**

Registration date

2023-06-19, 1402/03/29

Registrant information

Name

Zahra Ghafariyan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 2081

Email address

ghaffariandz971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-07-22, 1403/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Bromelain on Pain, Swelling and Trismus after Surgery in Orthognathic Patients

Public title
The Effect of Bromelain on Pain, Swelling and Trismus after Orthognathic Surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of the Disease by an Orthodontist and Surgery by a Maxillofacial Surgeon Willingness to Cooperate and Sign the Informed Consent Form after being fully informed about the objectives and method of conducting the study Not taking supplements for at least one month before
Exclusion criteria:
Suffering from chronic diseases such as diabetes mellitus, kidney failure, liver disorder and cancer Suffering from other autoimmune and inflammatory diseases Suffering from hormonal disorders, thyroid disorders Alcohol consumption and hookah use Smoking and being exposed to secondhand smoke chronically Unwillingness to participate in the study
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Since the two groups are supposed to have the same sample size, the block randomization method will be used in this study. Random block units will usually be used in order to balance the number of samples allocated to each study group. The size of the blocks will be chosen randomly, and each block contains an equal number of each group. The way to make the random sequence will be by the computer software "Random Allocation Software". Concealment of random allocation in sealed envelopes with random sequence will be done by a person who is not aware of the study process.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Participants, surgeons, orthodontists, and data and outcome analysts will not know how the groups were assigned. Placebo and bromelain capsules with a completely similar appearance are prepared by the pharmacist and provided to the researchers in plastic covers with the number specified by the pharmacist.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Ghoreishi Building, Daneshgah avenue.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Approval date
2023-03-11, 1401/12/20
Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1401.155

Health conditions studied

1

Description of health condition studied
Class III with maxilla deficiency and mandible prognathism
ICD-10 code
K07.1
ICD-10 code description
Anomalies of jaw-cranial base relationship

Primary outcomes

1

Description
Evaluation of swelling before and after intervention
Timepoint
Days 1, 7, 30 after surgery will be compared with these measurements before surgery and immediately after surgery
Method of measurement
to evaluate the swelling of the total length of the considered lines in the anatomical areas of the face will be used

2

Description
2. Assessment of pain before and after intervention
Timepoint
Days 1, 7, 30 after surgery will be compared with these measurements before surgery and immediately after surgery
Method of measurement
Visual analogue scale will be used in this evaluation

3

Description
Evaluation of mouth opening before and after the intervention
Timepoint
Days 1, 7, 30 after surgery will be compared with these measurements before surgery and immediately after surgery
Method of measurement
with a ruler from the incisal edge of the centrals in the state of maximum mouth opening

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Taking bromelain 200 mg powder inside the capsule three times a day for 8 days
Category
Treatment - Drugs

2

Description
Control group: Taking the powder inside the placebo capsule three times a day for 8 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Oral and maxillofacial surgery department, Mashhad dental school
Full name of responsible person
Seyedeh Maryam Omidkhoda
Street address
Oral and maxillofacial surgery department, Mashhad dental school, Vakilabad Blvd.
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2

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Seyedeh Maryam Omidkhoda
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3

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Seyedeh Maryam Omidkhoda
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Imam Reza Hospital, Ibn Sina Street, Doctor's Crossroads, Mashhad, Iran
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4

Recruitment center
Name of recruitment center
Mother Hospital
Full name of responsible person
Seyedeh Maryam Omidkhoda
Street address
Mother Hospital, 1st (Alley) The north of Bozorgmehr St, Sajad Blve, Mashhad, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Seyedeh Maryam Omidkhoda
Position
Associate professor
Latest degree
Specialist
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Dentistry
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Person responsible for scientific inquiries

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Associate professor
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Person responsible for updating data

Contact
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Mashhad University of Medical Sciences
Full name of responsible person
Zahra Ghafariyan
Position
Student
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A Level or less
Other areas of specialty/work
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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

All collected data would be shared for all researchers after the participants were unidentified.

When the data will become available and for how long

The access to data will be started 6 months after publication.

To whom data/document is available

The data would only be available for people working in academic institutions.

Under which criteria data/document could be used

It is allowed to use the data for meta-analysis and systematic reviews.

From where data/document is obtainable

The data can be obtained via email, from the corresponding researcher (Dr Seyedeh Maryam Omidkhoda). E-mail: omidkhodam@mums.ac.ir

What processes are involved for a request to access data/document

The new research proposal and the processes details should be e-mailed to corresponding researcher in order to get the access permission.

Comments