

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3806 7100

Email

omidkhodam@mums.ac.ir

2

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Seyedeh Maryam Omidkhoda

Street address

Ahmadabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9176999311

Phone

+98 51 3801 2602

Email

omidkhodam@mums.ac.ir

3

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Seyedeh Maryam Omidkhoda

Street address

Imam Reza Hospital, Ibn Sina Street, Doctor's Crossroads, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

omidkhodam@mums.ac.ir

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9187833678

Phone

+98 51 3704 8000

Email

omidkhodam@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyedeh Maryam Omidkhoda

Street address

Mashhad Dental School, Vakil Abad Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 917 112 8147

Email

omidkhodam@mums.ac.ir

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

Other areas of specialty/work

Dentistry

Street address

Mashhad Dental School, Vakil Abad Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 917 112 8147

Email

omidkhodam@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Sahand Samiee Rad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Mashhad Dental School, Vakil Abad Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 912 813 7859

Email

samieerads@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Ghafariyan

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Mashhad Dental School, Vakil Abad Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 930 210 7578

Email

ghaffariandz971@mums.ac.ir

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