Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Comparison of the effect of two drugs bromelain and ibuprofen in combination with acetaminophen and corticosteroid on pain and trismus after mandibular third molar surgery

Protocol summary

Study aim
The aim is to replace ibuprofen with a herbal compound with fewer side effects for pain relief in patients after wisdom teeth surgery

Design
Clinical trial with a control group, with parallel groups, double-blind, phase 1-2 on 80 patients. Stratification by simple randomization method using a sealed envelope will contain one bead (white bead of the intervention group, red bead of the control group).

Settings and conduct
Patients in need of mandibular third molar tooth surgery will be operated by a surgeon at Imam Reza Clinic (AS) in Shiraz. After surgery, patients are divided into two groups (intervention and control) by simple random allocation method. Medicines along with prescription instructions will be provided to patients. Patients receive the medicine in sealed envelopes with black cover that are coded (A and B). After starting the treatment, on days 1, 3 and 7, the pain level and degree of trismus of the patients are measured and recorded in a checklist. The study will be double-blind. Neither the patients nor the researcher will be aware of the type of drug given to the patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria include the need for mandibular third molar surgery, age between 17-35 years, and semi-occluded mesiangular mandibular third molar teeth. Patients who have taken painkillers or other drugs before surgery, have a history of drug addiction or are allergic to the drugs used in the study will not be included in the study.

Intervention groups
Intervention group: Bromelain will be given along with acetaminophen and corticosteroid after surgery Control group: After the surgery, ibuprofen along with acetaminophen and corticosteroids will be given

Main outcome variables
Main outcome variables of pain and trismus

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230131057290N1**
Registration date: **2023-08-14, 1402/05/23**
Registration timing: **prospective**

Last update: **2023-08-14, 1402/05/23**
Update count: **0**
Registration date
2023-08-14, 1402/05/23

Registrant information
Name
Ali Kochi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-08-23, 1402/06/01
Expected recruitment end date
2023-09-21, 1402/06/30
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two drugs bromelain and ibuprofen in combination with acetaminophen and corticosteroid on pain and trismus after mandibular third molar surgery

Public title

Comparison of the effect of bromoline drug on pain and trismus after dental surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Needing mandibular third molar surgery Age between 17-35 years Semi-embedded mesiangular mandibular third molar teeth

Exclusion criteria:

Patients who have taken painkillers or other drugs within 24 hours before surgery. have a history of addiction to drugs or painkillers Patients who are pregnant or breastfeeding, or have a known sensitivity to analgesics, common non-steroidal anti-inflammatories or cyclooxygenase-2 inhibitors. Those who have a history of nasal polyps, bronchospasm or angioedema caused by non-steroidal anti-inflammatories. Patients who were not able to take medicine orally

Age

From **17 years** old to **35 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize in this study, simple randomization method will be used. Randomization will be done using a sealed envelope containing a bead. If there is a white bead in the envelope, the patient will be in the intervention group, and if the envelope contains a red bead, he will be placed in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be a double-blind study. The evaluated drugs are placed in the same packages and will be provided to the patients along with the prescription instructions. Patients receive the medicine in sealed envelopes with black cover that are coded (A and B). Study drugs are administered to patients by an independent surgeon. Therefore, neither the patients nor the researchers will be aware of the type of drug given to the patients.

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

Zand St., Central Building of Shiraz University of Medical Sciences

City

shiraz

Province

Fars

Postal code

7134814336

Approval date

2023-07-05, 1402/04/14

Ethics committee reference number

IR.SUMS.DENTAL.REC.1402.040

Health conditions studied

1

Description of health condition studied

.

ICD-10 code

.

ICD-10 code description

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Primary outcomes

1

Description

pain

Timepoint

1, 3 and 7 days after surgery

Method of measurement

A visual analogue scale (VAS), with 10 points, will be evaluated from 0 for "no pain" to 10 for "worst possible pain".

2

Description

Trismus

Timepoint

1, 3 and 7 days after surgery

Method of measurement

The degree of trismus is also measured by measuring the inter-incisal distance using a measuring caliper and the results are reported with an accuracy of 0.01 mm.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 500 mg bromelain drug (Permon Amin Pharmaceutical Company) along with acetaminophen 325 mg every 8 hours (three times a day) and corticosteroids including dexamethasone 8 mg by intramuscular injection in one session immediately after surgery.

Category

Treatment - Drugs

2

Description

Control group: Ibuprofen drug 200 mg (Hakim Pharmaceutical Company) along with acetaminophen 325 mg every 8 hours (three times a day) and corticosteroid including dexamethasone 8 mg as intramuscular injection in one time immediately after surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Clinic in Shiraz

Full name of responsible person
Ilnaz Ghanbari

Street address
Prayer Square - Imam Reza Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Research assistant

Street address
Zand St., Central Building of Shiraz University of Medical Sciences

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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
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
Ilnaz Ghanbari

Position
Assistant Professor of Oral and Maxillofacial Surgery

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Ilnaz Ghanbari

Position
Assistant Professor of Oral and Maxillofacial Surgery

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Person responsible for updating data

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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
The data will remain confidential with the researcher and will only be used to carry out this research project.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available