Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison between Bromelain and Ibuprofen for postoperative pain control following dental implant placement surgery

Protocol summary

Study aim
The purpose of this study was to investigate the effect of Bromelain on Controling the pain after an implant surgery and to compare its effectiveness with the commonly used drug is ibuprofen.

Design
Two arm parallel group randomised clinical trial design of 40 patients with single blinded

Settings and conduct
Among the patients referring to Implant Department of Tabriz Faculty of Dentistry, individuals who are eligible, will be informed .The patients were randomly divided into two groups of 20. For the first group, Ibuprofen 400mg was prescribed 5 days every 8 hours.For the second group, Bromelin 500 mg was prescribed for 5 days every 8 hours. Post-operative pain is initial outcome that will be assessed at 1, 3, 6, days after surgery with using visual analog scale (VAS). Also, patients are not aware of the drug and which group they are in.

Participants/Inclusion and exclusion criteria
inclusion criteria : Applicants without illness over the age of 18 who have not consumed any medication in the last two weeks. Applicant to replacement of missing teeth with implants in the first and second premolar regions of the maxilla or mandible. Based on CBCT assessments, there is a sufficient amount of bone in the toothless areas without the need for recovery and reconstruction. exclusion criteria : Applicants with systemic diseases that are treated with other medications. Smokers and alcoholics. Applicants with poor oral hygiene. Applicants who need bone graft. Applicants who need more than two implants. Applicants with surgical duration more than 45 minutes.

Intervention groups
1-The group that received the Ibuplofen 400after dental implant surgery. 2-The group that received the Ibuplofen 400after dental implant surgery.

Main outcome variables
The main variable in this study is pain, which is measured by visual analog scale (VAS).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180513039628N1**
Registration date: **2018-08-29, 1397/06/07**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-29, 1397/06/07**
Update count: **0**

Registration date
2018-08-29, 1397/06/07

Registrant information

Name
Farhang Mahboub

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3335 5965

Email address
mahboubif@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-16, 1397/04/25

Expected recruitment end date
2019-01-05, 1397/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison between Bromelain and Ibuprofen for postoperative pain control following dental implant placement surgery

Public title
Comparison between Bromelain and Ibuprofen for postoperative pain control following dental implant placement surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Applicants without illness over the age of 18 who have not consumed any medication in the last two weeks. Applicant to replacement of missing teeth with implants in the first and second premolar regions of the maxilla or mandible. Based on CBCT assessments, there is a sufficient amount of bone in the toothless areas without the need for recovery and reconstruction.

Exclusion criteria:
Applicants with systemic diseases that are treated with other medications Smokers and alcoholics Applicants with poor oral hygiene Applicants who need bone graft Applicants who need more than two implants Applicants with surgical duration more than 45 minutes

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization of the samples is according to the expert's opinion using the Randlist software

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients are aware of the two generic groups but they are not aware which group they are in.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee in biomedical researchs of Tabriz University of Medical Sciences

Street address
No.2 central buiding, Tabriz University of Medical Sciences, Golgasht Ave.

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Approval date
2017-08-14, 1396/05/23

Ethics committee reference number
IR.TBZMED.REC.1396.476

Health conditions studied

1

Description of health condition studied
Pain control following dental implant placement surgery

ICD-10 code
K00-K14

ICD-10 code description
Diseases of oral cavity, salivary glands and jaws

Primary outcomes

1

Description
pain intensity

Timepoint
day 1, 3 and 6 after surgery

Method of measurement
Visual analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group : in intervention group Bromelin ,500 mg (Bromelain500-Parmoon Amin -Iran-Tehran) was prescribed an oral tablet for 5 days every 8 hours.Post-operative pain is initial outcome that will be assessed at 1, 3, 6, days after surgery with using visual analog scale (VAS).

Category
Treatment - Drugs

2

Description
Control group:in control group , Ibuprofen 400mg (Ibuprofen400-Abidi-Iran-Tehran) was prescribed an oral tablet for 5 days every 8 hours. Post-operative pain is initial outcome that will be assessed at 1, 3, 6, days after surgery with using visual analog scale (VAS).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry
Full name of responsible person
Farhang Mahboub
Street address
Faculty of Dentistry, Golgasht Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 41 3335 5965
Email
mahboubif@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Abolghasem Jouyban
Street address
No.2 central buiding, Tabriz University of Medical Sciences, Golgasht Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Phone
+98 41 3334 1249
Email
mahboubif@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Farhang Mahboub
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Faculty of Dentistry, Golgasht Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 41 3335 5965
Fax
Email
mahboubif@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Farhang Mahboub
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Person responsible for updating data

Contact

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The total potential data can be shared after unidentifiable Applicants.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Results are available to researchers and practitioner in the industry.

Under which criteria data/document could be used

No specific requirements.

From where data/document is obtainable

It can also be accessed via email. mahboubif@tbzmed.ac.ir

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

After sending the email, you can access it utmost a month later.

Comments