

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 Controlling 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 Ibuprofen 400after dental implant surgery. 2-The group that received the Ibuprofen 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 researches of Tabriz University of Medical Sciences

Street address

No.2 central building, 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 Bromelain ,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.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Abolghasem Jouyban

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

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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