Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of anti-inflamatory effect of anaheal 500 (Bomelain 500) and ibuprofen 400 in mandibular third molar surgery

Protocol summary

Study aim
Anti-inflamatory effect of anaheal 500in mandibular third molar surgery Determination of the effect of Anaheal on pain, trismus, ecchymosis after surgery Comparison of each of the above variables in the groups of Anaheal and Ibrophon 400 after surgery Incidence of dry socket in all groups

Design
non-Randomised, superiority, parallel group trial with double blinded outcome assessment.

Settings and conduct
The place of the study is dental clinic of babol university of medical sciences, where the patients and the main investigators are blinded by the envelopes of medicines by the pharmacist.

Participants/Inclusion and exclusion criteria
The population under study are those who refer to the clinic of the Faculty of Dentistry of Babol University of Medical Sciences in order to surgical removal of mandibular third molar. The number of samples based on similar studies, are 50 patients aged between 15 to 25 years old and candidates for mandibular third molar surgery. Patients are divided into two groups of recipients of Anaheall (Bromelin) and an ibuprofen 400 receptor. Non-admission criteria for our study include an adverse drug reaction to an anaheal or ibuprofen 400, smoking, taking some medications such as corticosteroids and bisphosphonates, diseases like diabetes, anemia, or other immunosuppressive diseases. hemorrhagic diseases, or the use of anticoagulant drugs, contraindication for adrenalin use, pregnancy, radiotherapy in the head and neck, and also the presence of pericoronitis or any pathological lesions associated with third molar teeth. The impacted wisdom teeth are classified according to Pell & Gregory Classes I, II-A, B and Class III and C are excluded.

Intervention groups
Patients are divided into two groups of recipients of Anaheal(Bromelin) and ibuprofen400 receptor, size of each groups are 25.

Main outcome variables
Replacing Ibuprofen400 with Anaheal After Surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150428021984N2**
Registration date: **2018-06-24, 1397/04/03**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-24, 1397/04/03**
Update count: **0**

Registration date
2018-06-24, 1397/04/03

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3222 7667

Email address
r.frooghi@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2018-08-21, 1397/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of anti-inflamatory effect of anaheal 500 (Bomelain 500) and ibuprofen 400 in mandibular third molar surgery

Public title
effectiveness of anaheal 500 (Bomelain 500) in mandibular third molar surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The population under study are peoples who refer to the clinic of the Faculty of Dentistry of Babol University of Medical Sciences in order to surgical removal of mandibular third molar. The impacted wisdom teeth are classified according to Pell & Gregory Classes I, II-A, B. Impacted teeth need to remove bones for better access to the crown of the tooth

Exclusion criteria:
Undesirable reaction to anaheal 500 or ibuprofen 400 smoking Taking some medicines like corticosteroids and basophosphonates Diseases like diabetes, anemia, or other immunosuppressive illnesses, hemorrhagic disease or taking anticoagulants Contraindication of adrenaline intake pregnancy History of radiotherapy in the head and neck area no paricoronitis or any pathological lesions associated with third molar teeth Classes III and C of The pell & gregory classes are excluded

Age
From **15 years** old to **25 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The drugs of the two groups are blided and coded by a colleague of a pharmacist.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics committee of babol university of medical sciences

Street address
babol, nooshirvani blvd, babol university of medical sciences

City
babol

Province
Mazandaran

Postal code
۴۷۱۷۶-۴۷۷۴۵

Approval date
2018-03-06, 1396/12/15

Ethics committee reference number
IR.MUBABOL.REC.1397.001

Health conditions studied

1

Description of health condition studied
inflamation of mandibular third molar surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Unwillingness to participate in the study

Timepoint
before surgery

Method of measurement
Based on consent form

2

Description
No effect of the studied drug

Timepoint
After reviewing of datas

Method of measurement
recorded datas

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: anaheal 500
Category
Treatment - Drugs

2

Description
Intervention group: ibuprofen 400
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
dental clinic of babol university of medical sciences
Full name of responsible person
علی محمدی - دکتر رامین فروغی
Street address
nooshirvani
City
babol
Province
Mazandaran
Postal code
۴۷۱۷۶-۴۷۷۴۵
Phone
+98 11 3219 9592
Email
ali.mus@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
dr hossein najafzade varzi
Street address
nooshirvani blvd.
City
babol
Province
Mazandaran
Postal code
4136747174
Phone
+98 11 3219 0557
Email
najafzadehvarzi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
ali mohammadi
Position
student
Latest degree
A Level or less
Other areas of specialty/work
student
Street address
nooshirvani blvd.
City
babol
Province
Mazandaran
Postal code
4717647745
Phone
+98 11 3219 9592
Email
ali.musm@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
ali mohammadi
Position
student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
nooshirvani blvd.
City
babol
Province
Mazandaran
Postal code
4717647745

Phone
+98 91132291408
Email
ali.musm@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
ali mohammadi
Position
student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
nooshirvani blvd.
City
babol
Province
Mazandaran
Postal code
4717647745
Phone
+98 11 3229 1408
Email
ali.musm@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available