

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Dec 2019

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

Protocol summary

Study aim

Anti-inflammatory effect of anaheal 500 in 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 Ibuprofen 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 Anaheal (Bromelain) 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 adrenal 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 (Bromelain) and ibuprofen 400 receptor, size of each group is 25.

Main outcome variables

Replacing Ibuprofen 400 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-inflammatory 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

inflammation 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

Type of organization providing the funding

Academic

Recruitment centers**1****Recruitment center****Name of recruitment center**

dental clinic of babol university of medical sciences

Full name of responsible person

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Phone

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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

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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**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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Latest degree

A Level or less

Other areas of specialty/work

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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