Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Randomize Clinical trial Comparison of the effect of Ibuprofen and Anaheal on pain control after periodental surgery

Protocol summary

Summary

The purpose of this study is comparing two Analgesics, Ibuprofen and Anaheal after periodontal surgery. Double-blinded clinical trial is done on 22 patients who have visited period ontology part of faculty dentistry of Tabriz university of medical science, according to the inclusion criteria (patients who need Mucoperiosteal flap without bone surgery or with limited bone surgery in two half upper jaw) and exclusion criteria (asthma patient and etc.) and will be divided in two groups. In this study Ibuprofen 400 mg (control group) and Anaheal (intervention) are prescribed for patients an hour before the practice and six hours after the first dose. Drugs are packaged at Tabriz medicine faculty in the same capsules by third person in the group A and B. Open flap surgery is done on two quadrants of upper jaw with 4 weeks interval. Group A drugs are prescribed an hour before the first surgery and 6 hours after the first dose and so in the same way, patient will be consuming group B medicine for second surgery. Post-operative pain is initial outcome that will be assessed at 2, 4, 6, 8, 10, 12, 24 and 48 hours after surgery with using visual analog scale (VAS) and verbal rating scale (VRS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608301760N46**
Registration date: **2016-09-21, 1395/06/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-09-21, 1395/06/31

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Tabriz University of Medical Sciences

Expected recruitment start date

2016-08-02, 1395/05/12

Expected recruitment end date

2016-09-02, 1395/06/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomize Clinical trial Comparison of the effect of Ibuprofen and Anaheal on pain control after periodental surgery

Public title

Randomize Clinical trial Comparison of the effect of Ibuprofen and Anaheal on pain control after periodental surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who need Mucoperiosteal flap without bone surgery or with very limited surgery of two half maxillary bones Exclusion criteria: During the surgery outside for 45 minutes to 60 minutes; Patients with an allergy to any drugs or other NSA-IDs Ibuprofen and Anaheal; Asthma; A history of heart disease; Pregnancy; Patients with hemophilia; Gastrointestinal diseases such as peptic ulcer diseases; Kidney disease or liver; Coagulation disorders; Patients with systemic lupus erythematosus; Patients with any history of periodontal surgery in the last six months; Patients with severe fear and anxiety when visiting the dentist; Any analgesic use during the last 48 hours; Patients with age above 60 years; Alcohol and drugs; Total Rating Modified dental anxiety scale higher than nineteen

Age
To **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features
This study is a double blind, crossover clinical trial. That project and any patient from the beginning to the final analysis, the contents of packages A and B do not know.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical sciences

Street address
Tabriz University of Medical sciences

City
Tabriz

Postal code

Approval date
2016-08-01, 1395/05/11

Ethics committee reference number
IR.TBZMED.REC.1395.496

Health conditions studied

1

Description of health condition studied
Pain after periodontal surgery

ICD-10 code
K05.5

ICD-10 code description
Other periodontal diseases

Primary outcomes

1

Description
Pain

Timepoint
At 2, 4, 6, 8, 10, 12, 24 and 48 hours after surgery

Method of measurement
Visual Analogue scale(VAS) and Verbal Rating Scale(VRS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Groups: This group receive Anahel medicine after surgery one quaderant of the upper jaw. An hour before the surgery and six hours after one dose. Intensity of the pain will be assessed with VAS and VRS at 2,4,6,8,10,12,24 and 48 hours after surgery.

Category
Treatment - Drugs

2

Description
Control Groups: This group receive Ibuprofen medicine after surgery another quaderant of the upper jaw. An hour before the surgery and six hours after one dose. Intensity of the pain will be assessed with VAS and VRS at 2,4,6,8,10,12,24 and 48 hours after surgery

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Periodontology, Dentistry colleges of Tabriz

Full name of responsible person
Seyed Reza Kazemi

Street address
Dental colleges, Tabriz University of Medical Sciences

City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Shariar Shahi
Street address
Vice Chancellor for Research and Technology, Tabriz University of Medical Sciences
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research and Technology, Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty