

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Randomize Clinical trial Comparison of the effect of Ibuprofen and Anaheal on pain control after periodontal 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 periodontology 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3236 2282

##### Email address

zahra@mubabol.ac.ir

##### 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 periodontal surgery

##### Public title

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

**Name of organization / entity**  
Dental colleges of Tabriz

**Full name of responsible person**  
Seyed Reza Kazemi

**Position**  
Dental students

**Other areas of specialty/work**

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## Person responsible for scientific

## inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Other areas of specialty/work**

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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*