

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Comparison of effect of Novafen, Ibuprofen and Acetaminophen on pain relief after implant surgeries in posterior region of maxilla

#### Protocol summary

##### Summary

The aim of this research is to compare the analgesic effects of Novafen, Ibuprofen and Acetaminophen after implant surgery in the maxillary posterior region. The research method of the present investigation is randomized double-blinded approach. In this study, 36 patients (including three groups, n=12) referring to the Department of Implant, Faculty of Dentistry, Tabriz University of Medical Sciences, will be selected as statistical population of the study. Inclusion criteria of the study consist of conditions such as favorable hard and soft tissue in the implant region and no need for adjunctive surgeries such as sinus lift procedure. Exclusion criteria consist of sensitivity to the study drugs and taking any analgesics at least four hours before implant surgery. Group one will receive Ibuprofen tablets (400 mg every eight hours); group 2 will receive Acetaminophen tablets (500 mg every 8 hours); and group 3 will receive Novafen capsules (containing 325 mg of Acetaminophen, 200 mg of Ibuprofen and 40 mg of Caffeine, every eight hours). The first dose will be given immediately after surgery and the second dose will be taken 8 hours after the first dose. Using Visual Analgesic Scale (VAS), the patients' pain will be measured 3 hours after surgery and then the pain will be measured by Verbal Rating Scale (VRS) within 12, 24 and 48 hours after surgery. The main variable is pain relief after implant surgery by the three drugs mentioned above, which will be evaluated at 3-, 12-, 24- and 48-hour postoperative intervals.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016071614440N2**

Registration date: **2016-08-10, 1395/05/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-08-10, 1395/05/20

##### Registrant information

###### Name

Alli Zarandi

###### Name of organization / entity

Dental Faculty, Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1335 5921

###### Email address

zarandia@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research of Tabriz University of Medical Sciences

##### Expected recruitment start date

2016-07-17, 1395/04/27

##### Expected recruitment end date

2016-08-07, 1395/05/17

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of effect of Novafen, Ibuprofen and Acetaminophen on pain relief after implant surgeries in posterior region of maxilla

##### Public title

Comparison of effect of Novafen, Ibuprofen and Acetaminophen on pain relief after implant surgeries in

posterior region of the upper jaw

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria of the study: Informed consent for being included in the study; Candidate patients of implant surgery aged 18–40 years; The hard and soft tissue region should be favorable for implant; Implant replacement without any adjunctive surgery Exclusion criteria of the study: Suffering from a systemic disease; Addictions to alcohol or smoking or every psychotropic substance; Diagnosed sensitivity to NSAIDs, Caffeine or Acetaminophen; Consuming drugs interfering with Ibuprofen, Novafen or Acetaminophen; Receiving any type of analgesics at least four hours before implant surgery

### **Age**

No age limit

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

No information

### **Sample size**

Target sample size: 36

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

All drugs were selected from the same pharmaceutical company, packed in similar capsules in the Faculty of Pharmacology of Tabriz and then packed in uniform tins by a third person, classified in three groups of A, B and C. All the packs were labeled and coded randomly and each patient will receive a pack before implant surgery. The randomized codes were hidden from the researchers, nurses and the patients and will be kept in a safe place until the end of the study.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

##### **Street address**

Ethics Committee of Tabriz University of Medical Sciences, Vice Chancellor for Research of Tabriz

University of Medical Sciences, Tabriz University of Medical Sciences, Golgasht street, Tabriz

### **City**

Tabriz

### **Postal code**

51665-118

### **Approval date**

2016-06-15, 1395/03/26

### **Ethics committee reference number**

IR.TBZMED.REC.1395.215

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

implant surgery

#### **ICD-10 code**

-

#### **ICD-10 code description**

-

## **Primary outcomes**

### **1**

#### **Description**

Pain Relief after implant surgery

#### **Timepoint**

3h, 12h, 24h and 48h after implant surgery

#### **Method of measurement**

VAS( Visual Analgesic Scale) 3h after implant surgery;  
VRS( Verbal Rating Scale) 12h, 24h and 48h after implant surgery

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group 1: ibuprofen 400 milligram tablet, immediately after the surgery and every 8 hours for 2 days

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Intervention group 2: Novafen capsule (containing acetaminophen 325 mg, ibuprofen 200 mg and caffeine 40 mg) immediately after the surgery and every 8 hours for 2 days

#### **Category**

Treatment - Drugs

### 3

#### Description

Control group: Acetaminofen 500 miligram tablet, immediately after the surgery and every 8 hours for 2 days

#### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Department of Implant of Dental Faculty of Tabriz University of Medical Sciences

###### Full name of responsible person

ali zarandi

###### Street address

Department of Implant, Tabriz Dental Faculty, Tabriz University of Medical Sciences

###### City

Tabriz

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Vice Chancellor for Research of Tabriz University of Medical Sciences

###### Full name of responsible person

Mohammadreza Rashidi

###### Street address

Vice Chancellor for Research, Tabriz University of Medical Sciences, Golgasht street

###### 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 of 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

Department of Periodontics of Dental Faculty of Tabriz University of Medical Sciences

##### Full name of responsible person

Ali Zarandi

##### Position

Assistant Professor

##### Other areas of specialty/work

##### Street address

Department of Periodontics, Tabriz Dental Faculty, Tabriz University of Medical Sciences, Golgasht St

##### City

Tabriz

##### Postal code

5166614713

##### Phone

+98 41 1329 4312

##### Fax

+98 41 1334 6977

##### Email

dr.alizarandi@gmail.com

##### Web page address

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Department of Periodontics of Dental Faculty of Tabriz University of Medical Sciences

##### Full name of responsible person

Ali Zarandi

##### Position

Assistant Professor

##### Other areas of specialty/work

##### Street address

Department of Orthodontics, Tabriz Dental Faculty, Tabriz University of Medical Sciences, Golgasht St

##### City

Tabriz

##### Postal code

5166614713

##### Phone

+98 41 1329 4312

##### Fax

+98 41 1334 6977

##### Email

Dr.alizarandi@gmail.com

##### Web page address

### Person responsible for updating data

#### Contact

##### Name of organization / entity

Department of Periodontics of Dental Faculty of Tabriz University of Medical Sciences

##### Full name of responsible person

Ali Zarandi

##### Position

Assistant Professor

**Other areas of specialty/work**

**Street address**

Department of Periodontics, Tabriz Dental Faculty,  
Tabriz University of Medical Sciences, Golgasht St

**City**

Tabriz

**Postal code**

5166614713

**Phone**

+98 41 1329 4312

**Fax**

+98 41 1334 6977

**Email**

Dr.alizarandi@gmail.com

**Web page address**

**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*