

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Effect of preoperative administration of Novafen in pain relief after periodontal surgeries

#### Protocol summary

##### Summary

The aim of this study was to evaluate the effect of preoperative administration of Novafen in pain relief after periodontal surgeries. The target population of this study are patients who are Candidate for crown lengthening surgery and 70 patients of them will be selected. The patients will be divided into two groups randomly. This study will be double-blinded. The first group immediately before periodontal surgery receive Novafen capsules (containing 325 mg of acetaminophen, 200 mg of ibuprofen and 40 mg caffeine) and second group receive placebo (starch). After surgery, all patients will use ibuprofen. On the other hand, at least four hours before treatment, patients should not take other painkillers. Pain severity of patients will be recorded 30 minutes, 1 and 3 hours after surgery by VAS (visual analgesic scale) scale and one, two and three days later by VRS (verbal rating scale) scale. Patients with a history of systemic or mental disease; addiction to alcohol or any mind-altering substance; known sensitivity to NSAID, acetaminophen or caffeine will exclude from study. Finally the data will be analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015062822951N1**  
Registration date: **2015-08-04, 1394/05/13**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-08-04, 1394/05/13

##### Registrant information

Name

milad Ghanizadeh

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3335 5921

##### Email address

milad.ghanizadeh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2015-07-30, 1394/05/08

##### Expected recruitment end date

2015-08-23, 1394/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of preoperative administration of Novafen in pain relief after periodontal surgeries

##### Public title

administration of Novafen capsules for prevention of the postoperative pain

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: A consent to inclusion; In the age range 16 to 40 years; Patients candidate for crown lengthening surgery. Exclusion criteria: Systemic disease or mental; Addiction to alcohol or any mind-altering substance; Known sensitivity to NSAID, acetaminophen or caffeine.

##### Age

From **16 years** old to **40 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tabriz University of Medical Sciences

##### Street address

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz, Iran

##### City

Tabriz

##### Postal code

#### Approval date

2015-07-29, 1394/05/07

#### Ethics committee reference number

Tbzmed.rec.1394.370

## Health conditions studied

### 1

#### Description of health condition studied

Periodontal surgery

#### ICD-10 code

K00-K14

#### ICD-10 code description

Diseases of oral cavity, salivary glands and jaws

## Primary outcomes

### 1

#### Description

Pain severity

#### Timepoint

1,2 and 3 days after Intervention

## Method of measurement

Based on verbal rating scale

### 2

#### Description

Pain severity

#### Timepoint

30 minutes, 1 and 3 hours after Intervention

#### Method of measurement

Based on visual analgesic scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Patients will receive a Novafen capsules (containing 325 mg of acetaminophen, 200 mg ibuprofen and 40 mg caffeine) immediately before periodontal surgery. All drugs are manufactured by Alvay pharmaceutical company (Tehran, Iran) in blinded label packages. All of the patients after surgery only will use ibuprofen painkiller.

#### Category

Treatment - Drugs

### 2

#### Description

Patients will receive a Placebo (containing Starch) immediately before periodontal surgery. All drugs are manufactured by Alvay pharmaceutical company (Tehran, Iran) in blinded label packages. All of the patients after surgery only will use ibuprofen painkiller.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Professional Department of Periodontology, School of Dentistry, Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Atrabak Kashefi Mehr

##### Street address

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz, Iran

##### City

Tabriz

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Edliye Shirmohammadi

**Street address**

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz, Iran

**City**

Tabriz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Atabak Kashefimehr

**Position**

Specialist in Periodontics/ Academic Staff

**Other areas of specialty/work****Street address**

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz, Iran

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### Person responsible for scientific inquiries

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### Person responsible for updating data

**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hatef Mollazadeh

**Position**

Dentistry student

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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*