Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of preoperative administration of Novafen in pain relief after periodental 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 periodental 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 Alhavy 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 wiil receive a Placebo (containing Starch) immediately before periodontal surgery. All drugs are manufactured by Alhavy 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 Scienc

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
City
Tabriz
Postal code
Phone
+98 41 3544 0754
Fax
Email
milad.ghanizadeh@gmail.com
Web page address

Person responsible for scientific 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
City
Tabriz
Postal code
Phone
+98 41 3544 0754
Fax
Email
milad.ghanizadeh@gmail.com
Web page address

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
Other areas of specialty/work
Street address
Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street,Tabriz,Iran
City
Tabriz
Postal code
Phone
+98 41 3544 0754
Fax
Email
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