Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of comparison of analgesic effect of Novafen versus Ibuprofen on pain relief after periodontal surgery

Protocol summary

Summary

Objectives: The aim of this study is the comparison of analgesic effect of Novafen ® versus Ibuprofen on pain relief after periodontal procedures. Major inclusion and exclusion criteria: Patients at the age range of 16 to 40 years with chronic moderate to severe generalized periodontitis who requires pocket elimination surgery will be enrolled into the study; patients with systemic, mental or hemorrhagic diseases, patients with addiction to alcohol or any other psychoactive substances and patients with known sensitivity to non-steroidal anti-inflammatory drugs, acetaminophen or caffeine will be excluded from the study. Study population: a number of 70 patients with chronic generalized periodontitis who will randomly be assigned into two equal groups. Intervention: the patients in intervention group will be asked to use Novafen® capsules immediately after the surgery and every 6 hours for 3 days, the patients in control group will also be asked to use ibuprofen 400 milligrams tablets immediately after the surgery and every 6 hours for 3 days. Main outcome variables: toothache after 30 minutes, 1 and 3 hours, and after 1, 2 and 3 days after the surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070918425N1**
Registration date: **2014-09-01, 1393/06/10**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-09-01, 1393/06/10

Registrant information

Name

Amir reza Babaloo

Name of organization / entity

Faculty of dentistry,Tabriz university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison of analgesic effect of Novafen versus Ibuprofen on pain relief after periodontal surgery

Public title

Comparison of analgesic effects of Novafen versus ibuprofen on pain relief after periodontal surgeries.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: being at the age range of 16 to 40 years; suffering from chronic generalized periodontitis which requires pocket elimination surgery. Exclusion criteria: suffering from any systemic or mental diseases;

addiction to alcohol or any other psychoactive substance; known sensitivity to non-steroidal anti-inflammatory drugs, caffeine or acetaminophen; suffering from any hemorrhagic disorder.

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

Gender
Both

Phase
2-3

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
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences and health services

Street address
Central office of Tabriz University of Medical Sciences, Daneshgah street, Golgasht street, Tabriz, Iran

City
Tabriz

Postal code
5165687386

Approval date
2014-06-14, 1393/03/24

Ethics committee reference number
9340

Health conditions studied

1

Description of health condition studied
The correlation of analgesic effect of Novafen versus Ibuprofen on pain relief after periodontal surgeries.

ICD-10 code
K08.8

ICD-10 code description
Toothache NOS

Primary outcomes

1

Description
Toothache after periodontal pocket elimination surgery

Timepoint
After 30 minutes, 1 hour and 3 hours after surgery by visual analogue scale (VAS) and after 1,2 and 3 days after surgery by verbal rating scale (VRS)

Method of measurement
Visual analogue scale (VAS) and verbal rating scale (VRS)

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Ibuprofen 400 milligram tablets, immediately after the surgery and every 6 hours for 3 days

Category
Treatment - Drugs

2

Description
Intervention group: Novafen capsule (containing acetaminophen 325 mg, ibuprofen 200 mg and caffeine 40 mg) immediately after the surgery and every 6 hours for 3 days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dentistry clinic of Tabriz dentistry faculty

Full name of responsible person
Dr. Amirreza Babaloo

Street address
Periodontics ward, Dentistry clinic of Tabriz dentistry faculty, Tabriz faculty of dentistry, Daneshgagh street, Golgasht street, Tabriz, Iran

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for reserach, Tabriz university of medical sciences

Full name of responsible person
Dr. Seyyed Kazem Shakouri
Street address
Vice chancellor for reserach, Central building of Tabriz University of Medical Sciences, Daneshgah street, Golgasht street, Tabriz, Ira
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 reserach, 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

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Name of organization / entity
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Person responsible for updating data

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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