

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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

Country

Iran (Islamic Republic of)

Phone

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Email address

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

Periodontics ward, Tabriz faculty of dentistry

Full name of responsible person

Dr. Mohammadtaghi Chitsazi

Position

Associate Professor, Periodontist

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

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Tabriz faculty of dentistry

Full name of responsible person

Hamed Moradzadeh

Position

Student of dentistry

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

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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