

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Analgesic Efficacy of celecoxib Versus Prednisolone For the Prevention and Control of Pain after Periodontal Surgery.

Protocol summary

Summary

The objective of this study is to evaluate the analgesic efficacy of Celecoxib Versus Prednisolone for the prevention and control of pain after periodontal surgery. This study is a randomized, double-blind, cross-over, placebo-controlled trial, on 20 patients with generalized, moderate to severe chronic periodontitis, aged 20 years or older and have three mucoperiosteal flaps with minor osseous surgery under local anesthesia, at least 4 weeks apart. Each quadrant is randomly assigned to receive one of the following interventions: 200 mg Celecoxib one hour before surgery and 12 hours after the first dose, 10 mg Prednisolone one hour before surgery and 8 hours after the first dose, or placebo. The medications are coded and delivered to the patients by and individual not aware of the research process. The patients will fill out a visual analog scale (VAS) and a five-point verbal rating scale (VRS-5), every hour for the first 8 hours after surgery and at three time points during the day after the surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138709051081N2**

Registration date: **2009-10-19, 1388/07/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-10-19, 1388/07/27

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Secretary of Research and Technology of Faculty of Dentistry, GUMS

Expected recruitment start date

2009-06-22, 1388/04/01

Expected recruitment end date

2010-02-20, 1388/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Analgesic Efficacy of celecoxib Versus Prednisolone For the Prevention and Control of Pain after Periodontal Surgery.

Public title

Effect of celecoxib on the reduction of pain after periodontal surgery.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Otherwise healthy individuals having moderate to severe chronic periodontitis and Being a candidate for mucoperiosteal flap with minor osseous surgery in at least 3 quadrants of dentition Exclusion criteria: Diabetes mellitus, uncontrolled hypertension,

gastric ulcer, pregnancy or breast feeding, allergy to drugs consumed in the study, high risk for Infective Endocarditis

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features
Amount of local anesthetic injection is the same for all patients and Surgery is done by a singel practitioner. Visual analogue Scale and a five -point verbal rating Scale are used for pain measurment. To eliminate effects of anxiety on pain reported by the patients, a Modified Dental anxiety Scale is used.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences, Research Secretary

Street address

Namjoo Blv. GUMS Building

City

Rasht

Postal code

Approval date

2009-04-18, 1388/01/29

Ethics committee reference number

3/132/774/پ

Health conditions studied

1

Description of health condition studied

Pain after periodontal surgery

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes

1

Description

Pain severity

Timepoint

From the first hour after surgery for 8 hours, every hour, and at the morning, noon and night of the day after surgery (11 time points)

Method of measurement

visul analoge scale and, five-point verbal rating scale

Secondary outcomes

1

Description

Treatment of periodontal disease

Timepoint

One week after surgery

Method of measurement

Examination by an expert surgeon

Intervention groups

1

Description

Celecoxib, 200 mg capsule, one hour before surgery and the second dose, 12 hours after the first dose

Category

Treatment - Drugs

2

Description

Placebo, capsule first dose, one hour before surgery and the second dose, 8 hours after the first dose

Category

Treatment - Drugs

3

Description

Prednisolone tablet, 10 mg one hour before surgery and the second dose, 8 hours after the first dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontics, Dental Research Center, Faculty of Dentistry, Guilan University of Medic

Full name of responsible person
Golpar Radafshar
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for Research, Faculty of Dentistry,
Guilan University of Medical Sciences
Full name of responsible person
Nastaran Mirfarhadi
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Emam Khomeini Blv. Opp Pardis Hotel
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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, Faculty of Dentistry, Guilan
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
Guilan University of Medical sciences, School of
Dentistry, Research Center
Full name of responsible person
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Person responsible for updating data

Contact

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