Clinical Trial Protocol
Iranian Registry of Clinical Trials
30 Jul 2019

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
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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
None

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 single practitioner. Visual analogue Scale and a five-point verbal rating Scale are used for pain measurement. 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/

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
Visual analogue 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 Medicine
Full name of responsible person
Golpar Radafshar
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Sponsors / Funding sources
Person responsible for general inquiries

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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