

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The role of prophylactic ibuprofen and N-acetylcysteine on the levels of TNF- α and IL-6 in chronic periapical lesions

Protocol summary

Summary

Periapical lesions are inflammatory diseases that extend following bacterial canal infection. In this study, we are looking for the role of prophylactic ibuprofen and N-acetylcysteine on the levels of TNF- α and IL-6 in chronic periapical lesions. Periapical radiographs are taken using bisecting technique and patients with radiolucencies less than 1 cm are randomly assigned to one of following four groups to receive ibuprofen 400 mg, NAC600 mg, Ibuprofen 200+NAC600 mg, or placebo (starch). Medications are made using 500 mg gelatinous capsules. The pain severity is recorded using visual analog scale (VAS). Each patient receives 2 similar capsules 2 hours and 30 minutes prior sampling. Then, the patient is anesthetized, the tooth is isolated and the access cavity is provided. Canal preparation is done up to size #40 file for single rooted teeth and size #30 file for multi-rooted teeth. Irrigation with normal saline is done and the canal is dried with paper points. Two paper points with size 30 are inserted in the canal and each kept in place for 30 seconds for exudates sampling. For teeth with active drainage, the points are kept with shorter time. If blood is observed, the sample is excluded, and if the point is dry, a fine file (size 8 or 10) passes the foramen and lets the exudates come into the canal. The wet length of the paper point is recorded and the volume of the fluid is calculated using Shimauchi standard curve in μ l. the point is inserted in a microtube containing phosphate buffered saline (PBS) with 0.05% twin 20. They are vortexed for 1 minute, and centrifuged, and the supernatant is isolated and kept in-70°C. VAS is repeated 4, 8, 12 and 24 hours later. Samples are analyzed using ELISA and cytokine levels are compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008114547N1**

Registration date: **2010-03-20, 1388/12/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-03-20, 1388/12/29

Registrant information

Name

Samir Zahedpasha

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1222 4032

Email address

samirzahedpasha@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2010-03-20, 1388/12/29

Expected recruitment end date

2011-07-23, 1390/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The role of prophylactic ibuprofen and N-acetylcysteine on the levels of TNF- α and IL-6 in chronic periapical lesions

Public title

The effect of ibuprofen on chronic periapical lesions

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria: periapical lesions less than 1 cm, accessibility to whole canal length, signing written informed consent
Exclusion criteria: Presence of systemic disorder, pregnancy, breast feeding, menopause, drug intake during last 48 hours, smoking or drug abuse, alcohol intake during the last 3 days, any allergy

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafrooz street, Babol

City

Babol

Postal code

4717641367

Approval date

2010-06-22, 1389/04/01

Ethics committee reference number

811

Health conditions studied**1****Description of health condition studied**

chronic apical periodontitis

ICD-10 code

K04.5

ICD-10 code description**Primary outcomes****1****Description**

IL-6

Timepoint

2 hours after intervention

Method of measurement

enzyme-linked immunosorbent assay

2**Description**

TNF-ALPHA

Timepoint

2 hours after intervention

Method of measurement

enzyme-linked immunosorbent assay

Secondary outcomes**1****Description**

pain

Timepoint

4, 8, 12 and 24 hours after intervention

Method of measurement

visual analog scale

Intervention groups**1****Description**

Ibuprofen 400 mg in a 500 mg gelatinous capsule, 2 hours and 30 minutes prior to sampling

Category

Treatment - Drugs

2**Description**

NAC600 mg in a 500 mg gelatinous capsule, 2 hours and 30 minutes prior to sampling

Category

Treatment - Drugs

3**Description**

Ibuprofen 200 mg + NAC600 mg in a 500 mg gelatinous capsule, 2 hours and 30 minutes prior to sampling

Category

Treatment - Drugs

4

Description

Placebo (starch) in a 500 mg gelatinous capsule, 2 hours and 30 minutes prior to sampling

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of dentistry, Babol University of Medical Sciences

Full name of responsible person

Maryam Ehsani, Samir Zahedpasha

Street address

Babol

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Babol University of Medical Sciences

Street address

Babol

City

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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

Babol 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

Faculty of dentistry, Babol University of Medical Sciences,

Full name of responsible person

Samir Zahedpasha

Position

Resident

Other areas of specialty/work

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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