

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation of the effects of local injection of Dexamethasone on post endodontic pain

Protocol summary

Summary

Many patients suffer from mild, moderate or severe pain during or after root canal therapy. The purpose of this study was to evaluate the efficacy of supraperiosteal injection of dexamethasone into the periapical tissues to prevent postoperative pain associated with inflammation. In a triple-blind, placebo-controlled clinical trial, 60 patients with moderate or severe pain who are referred to dental school of Mashhad University of Medical Sciences participate in this study. All patients should have a tooth with clinical diagnosis of irreversible pulpitis or pup necrosis without signs of periapical abscess. After administration of local anaesthesia, the standard treatment of RCT complete. Then, one millilitre dexamethasone (8 mg 2 mL(-1)) or placebo was injected around the tooth. The severity of pain was assessed with regard to a modified visual analogue scale after 6, 12, 24 and 48 h. The data was analysed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109217608N1**
Registration date: **2012-12-28, 1391/10/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-28, 1391/10/08

Registrant information

Name

Neda Naghavi

Name of organization / entity

Dental Research Center

Country

Iran (Islamic Republic of)

Phone

+98 511882950115

Email address

naghavin@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University Of Medical Sciences

Expected recruitment start date

2012-02-09, 1390/11/20

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of local injection of Dexamethasone on post endodontic pain

Public title

Dexamethasone effect on post endodontic pain

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: healthy people(ASA I or II); people need endodontic treatment exclusion criteria: pregnant and lactating women; people under 18; patient with hormonal and infected disorders not related to dental problems; moderate or severe periodontal diseases; acute apical abscesses or acute apical periodontitis; retreatment cases

Age

From **18 years** old to **149 years** old

Gender

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

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

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee in Mashhad University of Medical Sciences

Street address

Ghoreishi Building, Daneshgah street, Mashhad

City

Mashhad

Postal code**Approval date**

2012-03-14, 1390/12/24

Ethics committee reference number

900607

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

tooth pain

ICD-10 code

K08.8

ICD-10 code description

Other specified disorders of teeth and supporting structures

Primary outcomes**1****Description**

pain value

Timepoint

before treatment, 6,12,24,48 hours after treatment

Method of measurement

VAS scale

Secondary outcomes

empty

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

in intervention group: infiltraton injection of Dexamethasone (4mg/1ml), after completion of root canal treatment in control group: infiltraton injection of placebo (1ml ofdistilled water), after completion of root canal treatment

Category

Treatment - Drugs

2**Description**

in control group: infiltraton injection of placebo (1ml ofdistilled water), after completion of root canal treatment

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faculty of Dentistry/ Mashhad University of Medical Science

Full name of responsible person

Dr Neda Naghavi

Street address

Faculty of Dentistry, Azadi square, Mashhad

City

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mozhdeh Ghandeharian

Street address

Dental School, Azadi Square, Mashhad

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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

Dental Research Center

Full name of responsible person

Dr. Neda Naghavi

Position

assistant professor of Dental Research Center

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Dental Research Center, Faculty of Dentistry

Full name of responsible person

Dr. Saeed Moradi

Position

Associate Professor of Endodontics

Other areas of specialty/work

Street address

Endodontics group, Dental School, Azadi Square

City

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