

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Ibuprofen and Ibuprofen/Dexamethasone Infiltration on Post-Operative Pain in Single Visit Endodontics

Protocol summary

Study aim

To compare the frequency of post-operative/post-obturation pain experienced by the patient with ibuprofen/ dexamethasone infiltration compared to ibuprofen alone in a single visit endodontic procedure.

Design

Single blinded , Randomized Controlled Trial (RCT)

Settings and conduct

Operative Dentistry Department of Islamic International Dental Hospital - Islamabad, Pakistan All patients were assigned randomly into two equal groups, group A and group B, using randomization codes in opaque sealed envelopes. In Group A, after RCT, single shot local infiltration of 0.5 mg dexamethasone was given in periapical area. In Group B, after RCT local infiltration of placebo was given. Both patient groups were prescribed ibuprofen 400mg three times a day. only the participants were blinded by the placebo infiltration .

Participants/Inclusion and exclusion criteria

INCLUSION : Patients of both genders aged 16-45 years with non-vital asymptomatic maxillary single rooted tooth with necrotic pulp. **EXCLUSION :** • Teeth having extensive intra canal calcification. • Teeth with incompletely formed apices. • Teeth requiring retreatment. • Taking analgesics, anti-inflammatory or tri-cyclic anti-depressants. 5 • Allergy to endodontic medication. • Teeth with grade II or III mobility (more than 2 mm)

Intervention groups

In Group A, after RCT, single shot local infiltration of 0.5 mg dexamethasone was given in periapical area. In Group B, after RCT local infiltration of silane (placebo) was given. Both patient groups were prescribed ibuprofen 400mg three times a day.

Main outcome variables

Pain reported by patient at the end of endodontic treatment after 24, 48 and 72 hours using Visual Analogue Scale (VAS).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230713058771N2**

Registration date: **2023-09-26, 1402/07/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-26, 1402/07/04**

Update count: **0**

Registration date

2023-09-26, 1402/07/04

Registrant information

Name

Asim Qureshi

Name of organization / entity

Ayub medical and dental college

Country

Pakistan

Phone

+92 340 9053423

Email address

asim@ayubmed.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-10, 1402/05/19

Expected recruitment end date

2024-01-10, 1402/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Ibuprofen and Ibuprofen/Dexamethasone Infiltration on Post- Operative Pain in Single Visit Endodontics

Public title

Effect of Ibuprofen and Ibuprofen/Dexamethasone Infiltration on Post- Operative Pain in Single Visit Endodontics

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients of both genders aged 16-45 years with non-vital asymptomatic maxillary single rooted tooth with necrotic pulp.

Exclusion criteria:

- Teeth having extensive intra canal calcification.
- Teeth with incompletely formed apices
- Teeth requiring retreatment
- Taking analgesics, anti-inflammatory or tri-cyclic anti-depressants
- Allergy to endodontic medication
- Teeth with grade II or III mobility (more than 2 mm)

Age

From **16 years** old to **45 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

After proper history taking , investigations and formal consent. Subject was considered in one of our two groups by random allocation (lottery method). In this method each subject was asked to pick a sealed envelope out of the total 90. Each sealed envelope marked which group the subject will be put in. This was concealed from the subject.

Blinding (investigator's opinion)

Single blinded

Blinding description

In Group A, after RCT, single shot local infiltration of 0.5 mg dexamethasone will given in periapical area. In Group B, after RCT local infiltration single shot of placebo(saline) 0.5 mg will be given at periapical area. (similar delivery method for both groups)Both patient groups were prescribed ibuprofen 400mg three times a day.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethical committee at Islamic International Dental Hospital

Street address

7th avenue G7/4 , Islamabad

City

Islamabad

Postal code

25000

Approval date

2023-08-04, 1402/05/13

Ethics committee reference number

IIDC/08/023

Health conditions studied

1

Description of health condition studied

non vital asymptomatic teeth with necrotic pulp that require endodontic treatment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

post operative pain

Timepoint

24, 48, 72 hours after procedure

Method of measurement

visual analog scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: group A ibuprofen/dexamethasone infiltration. for this group all participants were given a single infiltration of 0.5 mg dexamethasone at the periapical tissue region. After the completion of root canal therapy

Category

Treatment - Drugs

2

Description

Control group: group B. for this group of participants a single infiltration of 0.5 mg of normal saline (placebo) was given at the periapical region after completion of root canal therapy

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Operative Dentistry Department of Islamic International Dental Hospital - Islamabad, Pakistan

Full name of responsible person

Dr. ABID HUSSAIN

Street address

St. 41 7th Ave, G-7/4 G 7/4 G-7, Islamabad, Islamabad Capital Territory

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asimovtm@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic International Dental Hospital

Full name of responsible person

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qazii.abid@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic International Dental Hospital

Proportion provided by this source

5

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic International Dental Hospital

Full name of responsible person

Dr. ABID HUSSAIN

Position

RESIDENT

Latest degree

Bachelor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Islamic International Dental Hospital

Full name of responsible person

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Position

RESIDENT

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

collective data of all participants data (data sheet) will be made available. assuring that the data provided is de identified. .

When the data will become available and for how long

once it has been published. always available on demand

To whom data/document is available

any researcher, that contacts the corresponding author for data with valid justification

Under which criteria data/document could be used

For researcher only . But complete data sheets will be provided where authors seems the reason is justified.

From where data/document is obtainable

upon contact with the corresponding researcher. by mail asim@ayubmed.edu.pk. Dr asim qureshi

What processes are involved for a request to access data/document

a formal request to the author with proof of research activity on the same topic.

Comments