Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Pakistan

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+92 340 9053423

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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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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 identifed. .

When the data will become available and for how long
once it has been published. always availably on demand

To whom data/document is available
any researcher, that contacts the corresponding author for data with vailed 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