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Effect of Propolis paste as compared to Calcium hydroxide on post-root canal treatment pain when inserted in root canals of infected teeth

Submission date
18/06/2017

Recruitment status
No longer recruiting

Registration date
24/08/2017

Overall study status
Completed

Last Edited
18/09/2023

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dental pain is a significant factor that causes patient's to seek treatment. Non-surgical endodontic (for root canals) treatment is a major therapy to treat the pain and save the tooth. Pain control during this procedure is a challenging goal for dental practitioners. Patients with necrotic teeth (when the centre part of the tooth has decayed) have the highest rates of post-endodontic pain. To prevent this, different techniques have been used. Placing biocompatible (not harmful or toxic) medications with either antimicrobial (anti- bacteria) activity or anti-inflammatory (swelling) component or both inside the root canals is one of the main techniques to disinfect the canals and control the pain. Calcium hydroxide is the most common medicament (medication mixture), however it is ineffective against certain fungi and bacteria, lacks anti-inflammatory component and is controversial in preventing pain. Presently, focus of research has shifted towards natural alternatives that could be used. Propolis is an organic resinous (thick and sticky) substance obtained from bee hive. It is nontoxic, biocompatible, anti-inflammatory, anti-oxidant, and anti-microbial and is effective against certain bacteria and fungi. The aim of this study is to evaluate the effect of Propolis paste on post-endodontic pain in comparison to calcium hydroxide at different time intervals.

Who can participate?
Adults aged 20-40 years old who have a necrotic tooth and require a root canal

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive endodontic treatment but receive a calcium hydroxide in the root area. Those in the second group receive the Propolis paste in the root area during their endodontic treatment. Participants are followed to and rate their pain levels before surgery and again four, 12, 24, 48 and 72 hours after their treatment. The two different medicaments are compared to see how well they were able to treat pain.

What are the possible benefits and risks of participating?
There are no direct benefits with participating. There are no notable risks however, participants may be allergic to the propolis paste and therefore are not included in the stufy.

Where is the study run from?
1. Dow Dental College (Pakistan)
2. Dr. Ishrat-ul-ibad Khan Institute of Oral Health Sciences (Pakistan)
3. Dow International Dental College (Pakistan)

When is the study starting and how long is it expected to run for?
January 2017 to October 2018

Who is funding the study?
Investigator initiated and funded (Pakistan)

Who is the main contact?
Dr Juzer Shabbir

Contact information

Type(s)
Scientific

Contact name
Dr Juzer Shabbir

Contact details
Dow University of Health Sciences
Dr. Ishrat-ul-ibad Khan Institute of Oral Health Sciences
Gulzar-e-Hijri
Ojha Campus
SUPARCO road
KDA Scheme-33
Karachi
Pakistan
75270

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03723980

Secondary identifying numbers
SMB53

Study information

Scientific Title
Effect of Propolis paste as compared to Calcium hydroxide when used as an intracanal medicament in necrotic teeth on post-endodontic pain: a double-blind randomized clinical trial

Study objectives
Null hypothesis:
There will be no significant difference between Calcium hydroxide and Propolis paste in reducing and preventing post-endodontic pain.

Alternative hypothesis (HA):
There will be a significant difference between Calcium hydroxide and Propolis paste group in reducing and preventing post-endodontic pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board, 10/03/2017, IRB-847/DUHS/Approval/2017/52

Study design
Parallel group prospective double blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Condition as of 30/10/2018:
Necrosis of pulp

Previous condition:
Domain in healthcare is dentistry and the condition we will be studying is Necrotic teeth with symptomatic apical periodontitis

Interventions
Interventions as of 30/10/2018:
Control group: Calcium hydroxide
Intervention group: Propolis paste
Non-probability sampling will be done for sample recruitment and simple randomization for

group allocation. Random group allocation will be computer generated. with equal randomization (1:1). The patients and the principal researcher will be blinded from the type of intracanal medicament inserted.

Patient attending the diagnosis department of the hospital with complaint of pain and having necrotic teeth found on examination, requiring standard non-surgical endodontic treatment are selected by non probability sampling for the study with his/her consent. Participants are randomly allocated to one of two groups by computer generated simple randomisation.

Group 1 (Control group): In the 1st visit of non surgical endodontic therapy, the standard procedure is performed until root canal preparation is completed. Then participants receive calcium hydroxide as an intracanal medicament inserted in the canal. This is supplied in a paste like consistency by the manufacturer and approximately 2.5 mg of the medication is used in each canal. This is inserted with the help of lentulo-spirals. They are only inserted once and then temporary fillings are done inside the tooth.

Group 2 (Intervention group): In the 1st visit of non surgical endodontic therapy, the standard procedure is performed until root canal preparation is completed. Then participants receive Propolis paste as an intracanal medicament inserted in the canal. Propolis paste is made by mixing 200 mg of propolis powder with 0.3 ml of normal saline and then is inserted into the root canal. This is inserted with the help of lentulo-spirals. They are only inserted once and then temporary fillings are done inside the tooth.)

Patients are asked to mark their pain intensity pre-operatively on Visual Analogue Scale. Then after procedure, they are given the Visual Analogue scale and requested them to mark their pain intensity (score) at 4 hours, 12 hours, 24 hours, 48 hours and 72 hours. Participants are then recalled after a week, and the Visual Analogue Scales are collected and their medicaments are removed and they proceed with their standard endodontic treatment.

Previous Interventions:
Control group: Calcium hydroxide
Intervention group: Propolis paste
Non-probability sampling will be done for sample recruitment and simple randomization for group allocation. Random group allocation will be computer generated. with equal randomization (1:1). The patients and the principal researcher will be blinded from the type of intracanal medicament inserted.

Patient attending the diagnosis department of the hospital with complaint of pain and having necrotic teeth found on examination, requiring standard non-surgical endodontic treatment are selected by non probability sampling for the study with his/her consent. Participants are randomly allocated to one of two groups by computer generated simple randomisation.

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Group 2 (Intervention group): In the 1st visit of non surgical endodontic therapy, the standard procedure is performed until root canal preparation is completed. Then participants receive Propolis paste as an intracanal medicament inserted in the canal. Propolis paste is made by

mixing 1.5 mg of propolis powder with 1 ml of normal saline and then is inserted into the root canal. This is inserted with the help of lentulo-spirals. They are only inserted once and then temporary fillings are done inside the tooth.

Participants are followed up after their first visit to mark their pain intensity (score) pre-operatively, then at four hours, 12 hours, 24 hours, 48 hours and 72 hours. Participants are then recalled after a week, and their pains scores are collected and their medicaments are removed and they proceed with their standard endodontic treatment.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Propolis paste

Primary outcome measure
Primary outcome measure as of 30/10/2018:
1. Pain intensity measure: Visual Analogue Pain Scale. Difference of the pain scores between the two groups at different time intervals.

Previous primary outcome measure:
1. Pain score is recorded by the patient using the Visual Analogue Scale (VAS scale) at four, 12, 24, 48 and 72 hours
2. Number of patients reaching the full followup period without taking oral analgesic is measured using the Visual Analogue Scale (statistically analysed during processing (after VAS scales are collected from all of the patients) to know how many patients reached the full follow up period of 72 hours without taking any oral analgesic) at 72 hours

Secondary outcome measures
Secondary outcome measures as of 30/10/2018:
1. Acute increase in pain score (acute exacerbation of pain), an increase of 20 or more points on Visual Analogue Pain Scale from pain score of previous time interval will indicate that pain has increased significantly and will be reported as "flare-up".
2. Difference of pain score between different time intervals will be recorded pre-operatively, then at time intervals of 4 hours, 12 hours, day 2, day 3 and day 4. The comparison of mean pain scores of different time intervals will be made.
3. Difference of pain scores and pain quality between males and females. The mean pain score difference between males and females at different time intervals will be assessed, frequencies of pain quality; no or mild pain, moderate pain, severe pain, and extreme pain will be reported according to gender.
4. Difference of pain scores and pain quality between different age groups. Mean pain score difference between different age groups: 20 to 24; 25 to 29; 30 to 34; and 35 to 40 at different time intervals will be assessed. Frequencies of pain quality; no or mild pain, moderate pain, severe pain, and extreme pain will be reported according to age group.

Previous secondary outcome measures:
Types of oral analgesic is measured using VAS scale (which is based on oral analgesics prescribed according to differing intensities of pain) and evaluating what type of analgesics are taken the most in each group at 72 hours

Overall study start date
01/01/2017

Completion date
15/10/2018

Eligibility

Key inclusion criteria
Participant inclusion criteria as of 30/10/2018:
1. Aged 20-40 years
2. Both male and female both
3. Single rooted Necrotic teeth with symptomatic or asymptomatic periapical periodontitis having visible periapical widening or radiolucency without bone expansion (PAI index 2, 3 and 4)
4. Teeth with favorable root morphology
5. Teeth with closed apex

Previous participant inclusion criteria:
1. Aged 20-40 years
2. Both male and female both
3. Single rooted Necrotic teeth with symptomatic periapical periodontitis having visible periapical widening or radiolucency without bone expansion (PAI index 3 and 4)
4. Teeth with favorable root morphology
5. Teeth with closed apex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80 patients attending the dental OPD with complain of pain, having necrotic single rooted teeth requiring non surgical endodontic treatment

Total final enrolment
80

Key exclusion criteria
Participant exclusion criteria as of 30/10/2018:
1. Teeth with PAI index 1 and 5
2. Patients who are on antibiotics
3. Patient with recent trauma to the jaw
4. Teeth with open apex
5. Multi-rooted teeth
6. Vital teeth
7. Non-restorable teeth
8. Unfavorable root morphology (severely curved, dilacerated, severely sclerosed or obliterated)
9. Teeth associated with soft tissue abscess or swelling
10. Teeth with external and internal root resorption
11. Re-treatment cases
12. Periodontally compromised teeth (like mobile teeth and teeth with excessive bone loss)
13. Teeth requiring endodontic surgery
14. Teeth requiring non-surgical endodontic treatment of multiple teeth in the same or opposing quadrant
15. Medically compromised patients (ASA-III and above), patients with special communication needs or who doesn't understand urdu or English language
16. Patients allergic to bee pollen or honey products

Previous participant exclusion criteria:
1. Teeth with PAI index 1, 4 and 5
2. Patients who are on antibiotics
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15. Medically compromised patients (ASA-III and above), patients with special communication needs or who doesn't understand urdu or English language
16. Patients allergic to bee pollen or honey products

Date of first enrolment
01/10/2017

Date of final enrolment
24/04/2018

Locations

Countries of recruitment
Pakistan

Study participating centre
Dow Dental College
Dow University of Health Sciences
Baba-E-Urdu Road
Karachi
Pakistan
74200

Study participating centre
Dr. Ishrat-ul-ibad Khan Institute of Oral Health Sciences
Ojha campus
University Road
Karachi
Pakistan
74200

Study participating centre
Dow International Dental College
Korangi Road
Karachi
Pakistan
74200

Sponsor information

Organisation
Dow University of Health Sciences

Sponsor details
Dow University of Health Sciences
Baba-E-Urdu Road
Karachi
Pakistan
74200

Sponsor type
University/education

Website
http://www.duhs.edu.pk/

ROR
https://ror.org/01h85hm56

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal.

Intention to publish date
31/10/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		30/10/2018	30/10/2018	No	No
Basic results	version v2	13/11/2018	13/11/2018	No	No
Results article	results	09/01/2020	07/04/2020	Yes	No
Results article	effect of variables such as age, gender, and tooth type on postoperative endodontic pain	28/01/2021	18/09/2023	Yes	No