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Evaluation of the efficacy of irrigation with pomegranate peel extract and apple cider vinegar in disinfecting the necrotic root canals of primary teeth

Submission date
31/05/2023

Recruitment status
No longer recruiting

Registration date
02/06/2023

Overall study status
Completed

Last Edited
08/07/2025

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
This study aims to improve the effectiveness of root canal treatment in children's baby teeth by finding a safer and more pleasant alternative to sodium hypochlorite for treatment of a necrotic tooth.
A necrotic tooth refers to a tooth that has undergone tissue death or decay. It occurs when the dental pulp, which contains nerves and blood vessels, becomes infected or damaged to the point where it can no longer recover.
We will explore a new solution derived from pomegranate peel, which will be carefully prepared using a unique formula. Detailed information about this formula will be provided in published research. By utilizing this new solution, we hope to achieve better disinfection results and increase the success rate of endodontic treatment without the concerns of sodium hypochlorite's toxicity or unpleasant taste when it comes into contact with the oral cavity.

Who can participate?
Children aged 3 to 9 years old with a necrotic tooth.

What does the study involve?
In this study, we will irrigate the root canals of primary teeth with pomegranate peel extract in one group and apple cider vinegar in another group. We will compare the results of these two groups to a control group that uses sodium hypochlorite. To measure the effectiveness of each solution, we will count the number of colony-forming units (CFUs) present in the samples taken from the canals before and after irrigation with each solution. This will help us assess the disinfecting properties of pomegranate peel extract and apple cider vinegar compared to the standard sodium hypochlorite.

What are the possible benefits and risks of participating?
The potential benefits of participating in the study include the treatment of necrotic teeth with copious irrigation and disinfection, which will save the tooth from extraction. However, there is also a risk of treatment failure and the flare-up of the condition.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
March 2023 to March 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Anas Mando, dent.anasmando@gmail.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Anas Mando

ORCID ID
https://orcid.org/0009-0002-4586-9132

Contact details
Damascus University
Mezzeh highway
Damascus
Syria
-
+963 994374279
anas.mando@damascusuniversity.edu.sy

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2653

Study information

Scientific Title
In pediatric patients with necrotic primary teeth, what is the effect of irrigation with pomegranate peel extract compared to irrigation with apple cider vinegar on disinfecting the root canals

Study objectives
1. There are no significant differences between the pomegranate peel extract group and the control group in the ability to reduce the bacterial count in the canals of necrotic temporary teeth
2. There are no significant differences between the apple cider vinegar group and the control group in the ability to reduce the bacterial count in the canals of necrotic temporary teeth

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/03/2023, Directorate of Scientific Research and higher Studies (Damascus University, Damascus, Damascus Governorate, 22743, Syrian Arab Republic; +9630113392348; ap.srd@damascusuniversity.edu.sy), ref: none available

Study design
Single-center interventional double-blinded randomized controlled comparative clinical study

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Disinfecting the necrotic root canals of primary teeth

Interventions
A randomized double-blinded, controlled, comparative clinical study comparing the efficacy of pomegranate peel extract soaked in apple cider vinegar with sodium hypochlorite liquid and with apple cider vinegar in reducing bacterial counts in the canals of anterior primary teeth.

Sample description
The sample size was calculated using the G-Power program (3.1.9.4) at a confidence level of 95% and a level of significance of 0.05, and based on similar previous studies, the sample will consist of 45 necrotic anterior primary teeth (incisors, laterals and canines), and the sample will be randomly distributed into three groups (n=15) using https://www.randomizer.org/

The study will be conducted on children aged from 3-9 years, and each group consisting of 15 ages will be divided as follows:
1. The first group (n = 15): irrigation of the canals with pomegranate peel extract soaked with apple cider vinegar.
2. The second group (n = 15): irrigation of the canals with apple cider vinegar.
3. The third group (control) (n = 15): irrigated the canals with 3% sodium hypochlorite.

Randomization is carried out using https://www.randomizer.org.

Participants are followed up at 1 week.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Disinfection of the root canals is measured by counting colony-forming units (CFUs) from the cultivated samples taken from the canals before and after irrigation with each solution

Key secondary outcome(s))
Pain on biting measured using clinical examination at 1 week postoperatively

Completion date
30/03/2024

Eligibility

Key inclusion criteria
1. Children 3-9 years old.
2. Children who have not taken antibiotics during the past 2 months.
3. The teeth (primary incisors and canines show no signs of internal radical resorption.
4. Signs of a clinically necrotic tooth with secretion of pus or fistula.
5. Radiographical transparency around the root with resorption of less than one-third of the root.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Lower age limit
3 years

Upper age limit
9 years

Sex
All

Total final enrolment
45

Key exclusion criteria

1. Children who have taken antibiotics within the past two months.
2. The teeth of children with systemic diseases, in which any infection may affect the general health of the child.
3. Insufficient bony support or less than half of the root length remaining

Date of first enrolment
18/06/2023

Date of final enrolment
15/09/2023

Locations

Countries of recruitment
Syria

Study participating centre
Damascus university
Faculty of dentistry
Department of pediatric dentistry
Damascus
Syria
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Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)

University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from Dr Anas Mando, Dent.anasmando@gmail.com, and will be published as a supplement to the result publication

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/02/2025	08/07/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes