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Removing caries with chemical agents

Submission date 09/10/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 22/10/2024	**Overall study status** Completed	
Last Edited 22/10/2024	**Condition category** Oral Health	

Plain English summary of protocol
Background and study aims
Chemomechanical caries removal (CMCR) is a non-invasive dental procedure that uses chemicals to soften and remove decayed tooth tissue. Numerous CMCR agents have been developed and recent studies have investigated the use of bromelain in CMCR. The aim of this study was to compare the effectiveness of bromelain enzyme-based gels in three concentrations (10, 15 and 20%) with 2.4% sodium hypochlorite gel in CMCR.

Who can participate?
Children aged 6 to 10 years with caries

What does the study involve?
The bromelain gels were freshly prepared using different concentrations of bromelain (10, 15 and 20%), and the bromelain gel or sodium hypochlorite was applied to the cavity and left for 60 seconds. Once the gel turned cloudy, it was carefully scraped away with a spoon excavator, avoiding pressure. This procedure was repeated with all gels until the gel applied in the cavity remained clear. The number of applications required for complete caries removal and the total time taken were recorded. Finally, the cavities were restored using glass-ionomer cement.

What are the possible benefits and risks of participating?
This study will remove caries with a minimally invasive technique without the stress and anxiety which may associated with traditional methods of removing caries.

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

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

Who is funding the study?
Damascus University (Syria)

Who is the main contact?

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
DUUS-1634-08062023

Study information

Scientific Title
Efficacy of different concentrations of bromelain gel in removing carious lesions in primary teeth using the chemical-mechanical caries removal (CMCR) technique: an in vivo study

Study objectives
There is no significant difference in efficacy between the four groups of bromelain gel in different three concentrations and the sodium hypochlorite gel 2.4% group

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/06/2023, Ethical Committee and the Board of Scientific Research at the Faculty of Dentistry, University of Damascus (Damascus, Damascus, 00963, Syria; -; mohannad1.laflouf@damascusuniversity.edu.sy), ref: DUUS-1634-08062023

Study design
Randomized four-arm active-controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Caries

Interventions
A total of 60 primary canines were included in this clinical trial. Bromelain gel at concentrations formulated pharmaceutically for this study (10%, 15%, and 20%) was used and compared with 2.4% sodium hypochlorite gel in the chemical-mechanical caries removal (CMCR) technique. Each patient was randomly allocated to one of four groups using the website http://www.random.org. The removal of the lesion was confirmed by the clinician performing the application, a blinded external researcher, and a caries detector dye. The study evaluated the number of applications required for complete caries removal for each agent and the time taken for caries removal.

Intervention Type
Procedure/Surgery

Primary outcome measure
The number of applications required for the removal of caries to be completed was recorded and the total time taken was measured using a digital timer

Secondary outcome measures
Pain and acceptability of the process measured using the Sound, Eye and Motor (SEM) Scale after the end of the treatment

Overall study start date
01/05/2023

Completion date
01/07/2024

Eligibility

Key inclusion criteria
1. Healthy children with no systemic diseases, such as diabetes, congenital heart disease, or autoimmune disorders, are generally considered for routine dental care without additional medical considerations.
2. The child's level of behavior was positive and definitely positive according to Frankl’s behavior

rating scale.
3. With upper primary canine teeth exhibit class V carious lesions involving dentin on the vestibular surfaces, which do not involve the pulp while all teeth are vital and non-accidental, with no clinical signs of pulp involvement.
4. There are no malformations or developmental abnormalities of the teeth.

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. History of allergy to any of the materials used
2. Systemic diseases
3. Deep caries involving the pulp
4. Presence of edema or a fistula associated with the decayed tooth

Date of first enrolment
12/06/2023

Date of final enrolment
01/07/2024

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Damascus
Syria
00963

Sponsor information

Organisation
Damascus University

Sponsor details
Damascus
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Syria
00963
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not@provided.com

Sponsor type
University/education

Website
http://ror.org/03m098d13

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

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from rmakkieh@yahoo.com. IPD will be shared in accordance with ethical guidelines and the consent of the patients who participated in the study.

IPD sharing plan summary
Available on request