

Removing caries with chemical agents

Submission date 09/10/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/10/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/10/2024	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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

Contact name

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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

Damascus

Syria

00963

+963

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