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Evaluation of BRIX3000 and Carisolv in chemomechanical caries removal in immature permanent first molars

Submission date
06/11/2024

Recruitment status
No longer recruiting

Registration date
06/11/2024

Overall study status
Completed

Last Edited
04/06/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
This study aimed to assess and compare the efficacy of Brix 3000, Carisolv, and the conventional rotary-mechanical method for caries removal, as well as to evaluate the pain level and the requirement for local anesthesia during caries excavation in immature mandibular PFMs of pediatric patients aged 7 to 9 years. The conventional rotary instrumentation method is widely used and has demonstrated its efficacy. Nevertheless, this method presents multiple drawbacks, including damaging thermal impacts on the pulp tissue and unnecessary removal of tooth structure, as well as discomfort, anxiety, and fear caused by the associated noise and vibrations. Various alternative techniques have been established, including lasers, air abrasion, smart burs, and chemomechanical caries removal (CMCR) methods, to address these limitations. Recently, there has been growing interest in CMCR methods, alongside a shift towards non-surgical treatments to alleviate pain and anxiety, particularly for pediatric patients.

Who can participate?
Healthy pediatric patients aged 7-9 years old with radiographically confirmed lesions reaching the middle or inner third of the dentine (D2/3) in immature mandibular PFMs

What does the study involve?
A total of seventy-five specimens were assigned randomly to five groups. Grouping was as follows:
Group 1 (Carisolv): CMCR utilizing Carisolv (CarisolvTM, MediTeam AB, Sävedalen, Sweden), n = 15.
Group 2 (BRIX3000): CMCR utilizing BRIX3000 (BRIX3000®, BRIX Medical Science, Santa Fe, Argentina), n = 15.
Group 3 (Conventional method): Control group, caries excavation utlizing conventional rotary-mechanical method, n =15.

What are the possible benefits and risks of participating?
Benefits: Participants will receive a restorative treatment.
Risks: There is a risk that the treatment would be painful.

Where is the study run from?
Damascus University, Syria

When is the study starting and how long is it expected to run for?
September 2021 to October 2024

Who is funding the study?
Damascus University, Syria

Who is the main contact?
Dr. Mawia Karkoutly, mawia95.karkoutly@damascusuniversity.edu.sy, mawiamaherkarkoutly@hotmail.com

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
Nil known

Study information

Scientific Title

Comparative evaluation of BRIX3000 and Carisolv in chemomechanical caries removal in immature permanent first molars: A randomized controlled trial

Study objectives
The null hypothesis is that Brix3000, Carisolv, and the conventional rotary-mechanical method would be equally effective in caries removal and patient comfort.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/09/2021, The Biomedical Research Ethics Committee of the University of Damascus (Mezzeh Highway, Damascus, -, Syria; +963 992 647 528; not@provided), ref: N3182

Study design
Double-blind randomized parallel-group active-controlled trial with three arms

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic, Medical and other records

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Dental caries

Interventions
A total of seventy-five specimens were assigned randomly to five groups with the help of an online randomization tool https://www.randomizer.org/. The total number of sets consisted of 3, with each set containing 15 samples, and the range of numbers spanned from 1 to 45.
Grouping was as follows:
Group 1 (Carisolv): chemomechanical caries removal (CMCR) utilizing Carisolv (CarisolvTM, MediTeam AB, Sävedalen, Sweden), n = 15.
Group 2 (BRIX3000): CMCR utilizing BRIX3000 (BRIX3000®, BRIX Medical Science, Santa Fe, Argentina), n = 15.
Group 3 (Conventional method): Control group, caries excavation utlizing conventional rotary-mechanical method, n =15.
This was a double-blind study in which both participants and those assessing outcomes were unaware of the group assignments.

Intervention
After pediatric patients' enrollment and legal guardians signed informed consent, a periapical X-ray was captured for each immature mandibular PFM using an intraoral periapical sensor (i-sensor, Guilin Woodpecker Medical Instrument Co., LTD., Guilin, China) to ensure that lesions only reach the middle or inner third of the dentine. Topical anesthetic (Iolite, Dharma Research Inc., Florida, United States) was applied before applying the rubber dam to achieve adequate isolation. For the BRIX3000 group, the gel was used in the carious cavity for two minutes according to the manufacturer's instructions. Similarly, for the Carisolv group, the gel was applied according to the manufacturer's instructions for thirty seconds. The softened carious dentine was scraped utilizing a curette (CarisolvTM, MediTeam AB, Sävedalen, Sweden), and the procedure was repeated until the gel color became clear. For the conventional method group, a contra-angle handpiece (NAC-EC, NSK Nakanishi Inc., Tochigi-ken, Japan) was utilized to excavate dentine caries with a round tungsten carbide bur (Round E 0123, Dentsply Maillefer, Ballaigues, Switzerland). For all study groups, the caries detector (Caries Marker, VOCO GmbH, Lower Saxony, Germany) was applied for 10 seconds, and the procedure was repeated until all caries were removed and the dentin reached a firm texture and showed no signs of resistance. The cavities were restored with composite resin (TetricN-Ceram, Ivoclar Vivadent, New York, United States).

After caries excavation, the cavity was evaluated by two blinded examiners (ICC > 0.8). The efficacy of caries removal was recorded utilizing Ericson et al. scale by visual-tactile examination and utilizing the caries detector, the Ericson et al. scale score was presented as follows:
0 = Complete caries excavation.
1=Caries located at the base of the cavity.
2=Caries located at the base of the cavity and/or the wall.
3=Caries located at the base of the cavity and/or two walls.
4=Caries located at the base of the cavity and/or more than two walls.
5=Caries located at the base and the margins of the cavity and two walls.

Objective pain assessment
The Sound, Eye, Motor (SEM) scale was utilized to objectively assess pain during the excavation of caries. This SEM scale emphasizes the child's vocalizations, eye movements, and physical reactions as noted by external observers. It was evaluated by two blinded examiners (ICC > 0.8), and SEM scoring criteria was presented as follows:
Sound
1. Score "1" = Comfort. No sound.
2. Score "2" = Mild discomfort. Non-specific sound.
3. Score "3" = Moderate discomfort. Louder sound, specific verbal complaint.
4. Score "4" = Severe discomfort. Shouting, crying, and verbal complaints indicate severe pain.
Eye
1. Score "1" = Comfort. No sign.
2. Score "2" = Mild discomfort. Dilated eye without tears (anxiety sign).
3. Score "3" = Moderate discomfort. Tears, and sudden eye movements.
4. Score "4" = Severe discomfort. Heavy crying.
Motor
1. Score "1" = Comfort. Relaxed body.
2. Score "2" = Mild discomfort. Muscular contraction indicates pain.
3. Score "3" = Moderate discomfort. Sudden and random movements of body and hand.
4. Score "4" = Severe discomfort. Hand movements for defense, pulling head away.

Subjective pain assessment
The Wong-Baker FACES scale was utilized to evaluate the child's pain levels during caries

excavation by prompting them to select the face that best reflects their emotions. This scale features six faces that vary in expression, starting with the happy face at level 0, indicating no pain, and culminating with the crying face at level 10, which signifies the most intense pain.
Requirement of local anesthesia
Cases where anesthesia was requested during treatment were documented as follows:
• The child asked for anesthesia.
• The child did not ask for anesthesia.

Intervention Type
Procedure/Surgery

Primary outcome measure
The efficacy of caries removal was measured by two blinded examiners (ICC > 0.8) using the Ericson et al. scale by visual-tactile examination and utilizing the caries detector of the Ericson et al. scale after caries excavation

Secondary outcome measures
1. Objective pain assessment measured using the Sound, Eye, Motor (SEM) scale by two blinded examiners (ICC > 0.8), and SEM scoring criteria during the excavation of caries
2. Subjective pain assessment measured using the Wong-Baker FACES scale during caries excavation
3. Requirement of local anesthesia measured using data collected in the study records during caries excavation

Overall study start date
01/09/2021

Completion date
17/10/2024

Eligibility

Key inclusion criteria
1. Healthy pediatric patients aged 7-9 years old
2. Pediatric patients were classified as either definitely positive or positive based on Frankel’s behavior rating scale
3. Radiographically, lesions reaching the middle or inner third of the dentine (D2/3) were observed in immature mandibular PFMs
4. Caries lesions fell under ICDAS code 4

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit

9 Years

Sex
Both

Target number of participants
45

Total final enrolment
45

Key exclusion criteria
1. Special health care needs for pediatric patients
2. Immature mandibular PFMs were exhibiting pulpal and/or periodontal issues
3. Unintentional pulp exposure occurred during the excavation process
4. Immature mandibular PFMs with dental anomalies

Date of first enrolment
03/08/2024

Date of final enrolment
12/10/2024

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Mazzeh highway
Damascus
Syria
-

Sponsor information

Organisation
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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
01/02/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Mawia Karkoutly, Mawiamaherkarkoutly@hotmail.com. The type of data that will be shared includes anonymised demographic information that will be available after publication. Consent from participants was required and obtained.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/06/2025	04/06/2025	Yes	No