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Comparison of two dental isolation tools used during routine procedures: Rubber Dam and OptiDam

Submission date
15/07/2025

Recruitment status
No longer recruiting

Registration date
18/07/2025

Overall study status
Completed

Last Edited
12/09/2025

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to compare the ease of application, time for placement, patient satisfaction, and comfort during common use of the OptiDam versus the conventional rubber dam (CRD) in routine dental practice at Umm Al-Qura University Dental Teaching Hospital.

Who can participate?
Patients receiving dental treatment at Umm Al-Qura University Dental Teaching Hospital

What does the study involve?
Participants are randomly allocated to be treated with Rubber Dam or OptiDam during their dental treatment.

What are the possible benefits and risks of participating?
The possible benefits include improved comfort and efficiency, enhanced quality of care, and contribution to dental research with no extra costs. The risks involved are minimal and similar to those associated with the use of rubber dams in standard dental procedures. If you experience discomfort, the rubber dam can be adjusted or removed.

Where is the study run from?
Umm Al-Qura University (Saudi Arabia)

When is the study starting and how long is it expected to run for?
December 2024 to August 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

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Principal investigator

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Additional identifiers

Protocol serial number
HAPO-02-K-012-2024-12-2377

Study information

Scientific Title
A clinical comparison of the Rubber Dam and OptiDam in routine dental procedures at Umm Al-Qura University Dental Hospital

Study objectives
Compare between two isolation systems:
1. Ease of application
2. Time for placement
3. Patient satisfaction
4. Patient comfort

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/12/2024, Umm Al-Qura University Faculty of Dentistry Biomedical Research Ethics Committee (Taif Road, Al-abdiyyah, Makkah, 24353, Saudi Arabia; +966 (0)125270000; cscenter@uqu.edu.sa), ref: JTIR141124

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Safety

Health condition(s) or problem(s) studied
Moisture control during dental procedures

Interventions
Patients will be assigned to one of two groups (1:1) using computer-generated randomisation:
1. Conventional rubber dam (control group)
2. OptiDam (intervention group)

Treatment duration: each procedure will last 1 to 2 hours.
Follow-up duration: immediate post-procedure evaluation only.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Time to place isolation system, recorded by using a stopwatch starting at the initiation of isolation placement and ending when the isolation is stable in place and the tooth is ready for treatment
2. Operator preference assessed by questionnaire immediately after placing the isolation system
3. Patient comfort assessed using a Visual Analog Scale (VAS) immediately after the dental

procedure
4. Patient satisfaction assessed by questionnaire after the dental procedure, before patient discharge

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
17/08/2025

Eligibility

Key inclusion criteria
1. Systematically healthy patients: American Society of Anesthesiologists (ASA) I or Controlled ASA II
2. Undergoing routine dental procedures

Participant type(s)
Patient, Learner/student

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
15 Years

Upper age limit
60 Years

Sex
All

Total final enrolment
114

Key exclusion criteria
1. Latex allergy
2. Severe gag reflex

Date of first enrolment
10/12/2024

Date of final enrolment
07/08/2025

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Umm Al-Qura University
Taif Road
Al-Abdiyyah
Makkah
Saudi Arabia
24243

Sponsor information

Organisation
Umm al-Qura University

ROR
https://ror.org/01xjqrm90

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study are not expected to be made available, as the data can be verified for only validity purposes if required by an authority that has the right to check our result upon request from the author, Rashed Binqali. The data is quantitative data and will be stored in Dr. Omair M. Bukhari's office at Umm Al-Qura University for two years. The data can be accessed by the research team only. All data was taken from the participants after signing an electronic consent to use their data for the purpose of this study only.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes