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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**
Recruiting

**Registration date**
18/07/2025

**Overall study status**
Ongoing

**Last Edited**
16/07/2025

**Condition category**
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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 May 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Rashed Binqali, s441007974@uqu.edu.sa

# Contact information

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# Additional identifiers

**EudraCT/CTIS number**
Nil known

**IRAS number**

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
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

### Study design
Randomized controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

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

### Study type(s)
Safety

### Participant information sheet
https://forms.gle/VtEEBqEbZGPG3sf98

### 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 measure
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

### Secondary outcome measures
There are no secondary outcome measures

### Overall study start date
09/12/2024

### Completion date
11/11/2025

## 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

### Age group
Mixed

### Lower age limit
15 Years

### Upper age limit
60 Years

### Sex
Both

### Target number of participants
100

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

### Date of first enrolment
10/12/2024

### Date of final enrolment
01/09/2025

## Locations

### Countries of recruitment
Saudi Arabia

### Study participating centre
**Umm Al-Qura University**
Taif Road
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## Sponsor information

### Organisation
Umm al-Qura University

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### Sponsor type
University/education

### Website
https://uqu.edu.sa/english

**ROR**
https://ror.org/01xjqrm90

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

**Publication and dissemination plan**
The researchers aim to publish the study results in one publication as soon as they finish the study.

**Intention to publish date**
20/12/2025

**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