

# How dental pulp reacts after treatment: a tissue-level study comparing reversible and irreversible pulpitis in adult teeth

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| <b>Submission date</b><br>12/05/2025   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                                  |
| <b>Registration date</b><br>12/05/2025 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>14/05/2025       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

This study aims to evaluate the effectiveness of three materials (MTA, Bioceramic, and Biodentine) in treating teeth with pulpitis (inflamed pulp). Pulpitis can cause pain and may require tooth extraction. The study will test how well these materials help the tooth heal before extraction, which is planned for other clinical reasons.

### Who can participate?

Adults with teeth showing symptoms of reversible or irreversible pulpitis, and who are scheduled for tooth extraction for clinical reasons, are eligible to participate.

### What does the study involve?

Participants will undergo a pulpotomy, where the infected pulp is removed, and one of the study materials will be used to treat the tooth. The procedure will be followed by regular check-ups at one week and three months to monitor healing. The teeth will be extracted as planned.

### What are the possible benefits and risks of participating?

#### Benefits:

Potential to improve tooth healing. Regular follow-up care and monitoring.

#### Risks:

Pain, infection, or complications. The treatment may not succeed, requiring further procedures.

### Where is the study run from?

The Department of Endodontics, Faculty of Dentistry, University of Hama, Syria.

### When is the study starting and how long is it expected to run for?

February 2021 to October 2024

Who is funding the study?

This study has no external funding. This study is self-funded by the principal investigator and the Faculty of Dentistry, University of Hama

Who is the main contact?

1. Abdulghani Mardini, Abdalganymardini@gmail.com
2. Hasan Alzoubi, dr.hasan.alzoubi.93@gmail.com

### **Study website**

<https://hama-univ.edu.sy/newsites/dentist/>

## **Contact information**

### **Type(s)**

Principal Investigator

### **Contact name**

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### **Contact name**

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

UHHS-226-09022021/SRC-94

## **Study information**

**Scientific Title**

Histopathological and immunohistochemical evaluation of pulpal inflammatory responses following pulpotomy in mature permanent teeth with reversible and irreversible pulpitis

**Acronym**

HIPPI Study

**Study objectives**

The null hypothesis was that there are no differences between (MTA – Bioceramic - Biodentine) in inflammatory dental pulp responses after pulpotomy of mature permanent teeth with symptoms of reversible or irreversible pulpitis.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 09/02/2021, Scientific Research and Postgraduate Board of Hama University (Assi Square, Hama, 00000, Syria; +963 33 222 3790; webadmin@hama-univ.edu.com), ref: 226

**Study design**

Single-centre interventional double-blind randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Dental clinic

**Study type(s)**

Treatment

**Participant information sheet**

See study outputs table

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

Treatment reversible and irreversible pulpitis in mature permanent teeth

## Interventions

The clinical assessment began with a comprehensive evaluation including medical history, chief complaint, pulp sensitivity via cold testing (ethyl chloride), percussion testing for periapical condition, and assessment of periodontal status through gingival sulcus probing and mobility testing. Periapical radiographs were obtained to ensure full root visualization with at least 2 mm beyond the apex. Teeth diagnosed with reversible or irreversible pulpitis—based on clinical and radiographic findings—were selected. After patient consent, local anesthesia was administered and rubber dam isolation was achieved. Disinfection with 5.25% sodium hypochlorite was followed by caries removal, pulp chamber access, and coronal pulp amputation using sterile burs. Hemostasis within 10 minutes was a key inclusion criterion. Pulp wounds were treated with one of the three bioactive materials:

1. MTA (Control)
2. Bioceramic (Experimental)
3. Biodentine (Experimental)

This was followed by restoration with a base layer of Fuji IX GIC and final composite restoration. All procedures were conducted at the Department of Endodontics and Restorative Dentistry, Hama University. Participants with reversible or irreversible pulpitis were randomly assigned to one of three groups (MTA, Bioceramic, Biodentine) using computer-generated block randomization (block size = 6). An independent researcher created the sequence and prepared sealed, opaque envelopes to ensure allocation concealment. Envelopes were opened only after eligibility confirmation.

## Intervention Type

Procedure/Surgery

## Primary outcome measure

The severity of inflammation was measured using histology after a week and 3 months by examining inflammatory cells, and the severity of inflammation was classified as follows: score 0: There are no inflammatory cells at or adjacent to the site of exposure, score 1: slight inflammation; presence of a small number of inflammatory cells, score 2: moderate inflammation medium number of inflammatory cells, score 3: Acute inflammation; abundant presence of inflammatory cells.

## Secondary outcome measures

The expression of the inflammatory immune marker was measured after a week and 3 months using the amputation materials used according to the following index: score 0: no inflammation (no staining), score 1: mild inflammation (mild staining), score 2: moderate inflammation (moderate staining), score 3: severe inflammation (severe staining)

## Overall study start date

09/02/2021

## Completion date

28/10/2024

## Eligibility

### Key inclusion criteria

1. A mature permanent tooth indicated for extraction for orthodontic reasons that does not have any carious lesions for the reversible pulpitis groups
2. Mature permanent tooth requiring extraction (such as third molars) has deep carious lesions with clinical signs and symptoms of irreversible pulpitis (spontaneous or intermittent acute pain) for irreversible pulpitis groups
3. A positive response to pulp sensitivity tests with no signs of pulp necrosis (such as edema, fistula or severe sensitivity to percussion)
4. Restorable tooth without the need for a crown or posts, the gingival sulcus depth between 1-3 mm, and normal tooth mobility
5. The periapical radiograph showed a pulp chamber with relatively normal dimensions without degenerative activity (pulp stones, calcification, severe canal narrowing in the vertical direction)
6. Absence of periapical and furcation radiolucency
7. Absence of internal or external absorption

**Participant type(s)**

Patient

**Age group**

Mixed

**Lower age limit**

16 Years

**Upper age limit**

35 Years

**Sex**

Both

**Target number of participants**

60

**Total final enrolment**

60

**Key exclusion criteria**

1. History of immune or bleeding diseases
2. Medications that may affect the metabolism
3. Uncontrolled pulp hemorrhage after pulpotomy procedures within 10 minutes of hemostasis
4. Abnormal color and appearance of the pulp tissue
5. Absence of hemorrhage or little hemorrhage in a dark red color after pulp exposure or after pulpotomy procedures

**Date of first enrolment**

25/01/2022

**Date of final enrolment**

15/03/2024

# Locations

## Countries of recruitment

Syria

## Study participating centre

**Abdulghani Mardini**

Assi Square

Hama

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## Study participating centre

**Hasan Alzoubi**

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# Sponsor information

## Organisation

Damascus University

## Sponsor details

Baramkeh

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## Sponsor type

University/education

## Website

<https://www.damascusuniversity.edu.sy/>

## ROR

<https://ror.org/03m098d13>

# Funder(s)

Funder type  
Other

Funder Name  
Investigator initiated and funded

## Results and Publications

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

Intention to publish date  
01/06/2025

Individual participant data (IPD) sharing plan  
The datasets generated during and/or analysed during the current study are/will be available upon request from Hasan Alzoubi, dr.hasan.alzoubi.93@gmail.com.

Data Availability:  
IPD will be made available to researchers after the study’s final publication in a de-identified format to protect participant privacy.

Access:  
Researchers can request access to the data by submitting a research proposal for review by the study's ethics or data access committee.

Timeline:  
Data will be shared within [6 months] after the study’s final publication.

Security:  
Data will be anonymized and stored in secure, password-protected databases with access restricted to authorized personnel.

Ethics and Consent:  
Participants have given consent for their de-identified data to be used for future research. Data sharing will comply with the study’s ethical guidelines.

IPD sharing plan summary  
Available on request

### Study outputs

| Output type                                   | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> |         |              | 14/05/2025 | No             | Yes             |