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Comparing two ways of cleaning root canals to see which better reduces harmful bacteria during dental treatment

Submission date
21/11/2025

Recruitment status
No longer recruiting

Registration date
25/11/2025

Overall study status
Completed

Last Edited
25/11/2025

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 effectiveness of multi-step versus single-step root canal irrigation protocols in reducing bacterial DNA and RNA levels.

Who can participate?
Eligible participants are patients requiring root canal treatment who meet inclusion criteria and provide informed consent.

What does the study involve?
Participants will receive root canal treatment using one of two irrigation methods. Bacterial samples will be collected before and after treatment to assess bacterial load reduction.

What are the possible benefits and risks of participating?
Participants may benefit from optimized root canal treatment techniques. Risks include mild discomfort or sensitivity related to standard dental procedures.

Where is the study run from?
The study is conducted at the College of Dentistry, Mustansiriyah University (Iraq)

When is the study starting and how long is it expected to run for?
The study starts 08/05/2024, last enrolment 10/04/2025 and completed 18/12/2025 .

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
The main contact is Omar Talib Khaleefah, reachable at omr_ta@yahoo.com for any study-related questions.

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Comparative evaluation of multi-step versus single-step root canal irrigation protocols on reduction of bacterial DNA and RNA levels: a randomized controlled clinical trial

Study objectives
To compare the efficacy of conventional multi-step irrigants (sodium hypochlorite and EDTA) against single-step Triton irrigants in reducing bacterial DNA and RNA levels within root canals.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/05/2024, College of Dentistry Research Ethics Committee (Mustansiriyah University, Baghdad, -, Iraq; -; mucodrec@gmail.com), ref: REC198

Primary study design
Interventional

Study design
Parallel superiority, double-blind randomized controlled trial

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
Maxillary central incisors with necrotic pulp (non-responsive to sensitivity testing), asymptomatic apical periodontitis

Interventions
Procedure and Bacterial Sampling:
28 patients included, All teeth follow strict aseptic measures, including plaque removal and disinfection with 30% H2O2 followed by 2.5% NaOCl, which is then inactivated with 5% sodium thiosulfate. Control samples using sterile paper points verify the sterility of the disinfected tooth surface before anesthesia and isolation. After access cavity preparation and complete removal of caries and restoration, the cavity undergoes the same disinfection protocol, and another control sample is obtained.

Patients are randomly assigned to two groups based on irrigation technique:

Group 1: Multi-Step (NaOCl/EDTA, n=14)

Group 2: Single-Step (Triton, n=14)

Before the first sampling (S1), a K-file #15 confirms working length using radiographs and an apex locator. Three sterile paper points are consecutively introduced to full canal length and retained for 60 seconds. Chemomechanical preparation follows using modified NiTi instruments, with irrigation according to group assignment and irrigants neutralized by 5% sodium thiosulfate.

The second sampling (S2) is conducted immediately after chemomechanical preparation using the same sampling method. All samples are collected for bacterial DNA and RNA analysis.

Intervention Type
Other

Primary outcome(s)
1. Bacterial DNA levels measured using polymerase chain reaction (PCR) analysis at baseline (before chemomechanical preparation) and immediately after chemomechanical preparation

2. Bacterial RNA levels measured using reverse transcription polymerase chain reaction (RT-PCR) analysis at baseline (before chemomechanical preparation) and immediately after chemomechanical preparation

Key secondary outcome(s)

Completion date
18/12/2025

Eligibility

Key inclusion criteria
1. Maxillary central incisors with necrotic pulp (non-responsive to sensitivity testing)
2. Asymptomatic apical periodontitis, confirmed by periapical radiographs
3. Patients aged 18–60 years

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment
28

Key exclusion criteria
1. Symptomatic teeth (pain, tenderness, swelling)
2. Immature roots
3. Antibiotic use within 3 months
4. Systemic disease
5. Inability to isolate with a rubber dam
6. Periodontal pockets >3 mm
7. Root fractures
8. Severe decay

Date of first enrolment
08/05/2024

Date of final enrolment
10/04/2025

Locations

Countries of recruitment
Iraq

Study participating centre
outpatient Postgraduate Clinic, College of Dentistry, Mustansiriyah University
Baghdad
Iraq
10052

Sponsor information

Organisation
Mustansiriyah University

ROR
https://ror.org/05s04wy35

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Omar Talib Khaleefah (omr_ta@yahoo.com)

IPD sharing plan summary
Available on request