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Effect of XP-endo finisher on microbial root canal flora after using multiple irrigation protocols

Submission date 16/04/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/04/2025	**Overall study status** Completed	
Last Edited 28/04/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
This study focuses on root canal infections, which are caused by bacteria and can lead to serious dental problems. The goal is to find the best way to clean the root canal using different solutions. Researchers are comparing three methods: using 5.25% sodium hypochlorite alone, combining it with 2% chlorhexidine, and combining it with QMIX. They are also looking at whether using a special tool called the XP-endo Finisher makes a difference.

Who can participate?
People who are between 20 and 40 years old, have no preoperative pain, have necrotic teeth, have a periapical radiolucency of 1-5 mm in diameter, and haven't taken antibiotics in the past three months.

What does the study involve?
The study involves treating 60 single-rooted teeth in patients and 60 freshly extracted single-rooted teeth in a lab. The teeth are divided into six groups, each using different cleaning methods with or without the XP-endo Finisher.

What are the possible benefits and risks of participating?
The main benefit is improved dental health and appearance. The risks are minimal and almost non-existent.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
March 2021 to March 2025.

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Farah Estefane, estefanfarah3@gmail.com

Contact information

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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
A comparative study of several final irrigation protocols and the use of XP-endo finisher in changing of the microbial root canal flora

Study objectives
H_1: There is no significant difference in bacterial count and antibacterial efficacy against Enterococcus faecalis after root canal irrigation using sodium hypochlorite (NaOCl) without XP-endo Finisher compared to irrigation using sodium hypochlorite with XP-endo Finisher.

H_2: There is no significant difference in bacterial count and antibacterial efficacy against Enterococcus faecalis after root canal irrigation using sodium hypochlorite (NaOCl) with XP-endo Finisher compared to irrigation using sodium hypochlorite without XP-endo Finisher.

H_3: There is no significant difference in bacterial count and antibacterial efficacy against Enterococcus faecalis after root canal irrigation using sodium hypochlorite (NaOCl) combined with QMiX without XP-endo Finisher compared to irrigation using sodium hypochlorite with QMiX with XP-endo Finisher.

H_4: There is no significant difference in bacterial count and antibacterial efficacy against Enterococcus faecalis after root canal irrigation using sodium hypochlorite (NaOCl) combined with QMiX with XP-endo Finisher compared to irrigation using sodium hypochlorite with QMiX without XP-endo Finisher.

H_5: There is no significant difference in bacterial count and antibacterial efficacy against Enterococcus faecalis after root canal irrigation using sodium hypochlorite (NaOCl) combined with chlorhexidine (CHX) without XP-endo Finisher compared to irrigation using sodium hypochlorite with chlorhexidine with XP-endo Finisher.

H_6: There is no significant difference in bacterial count and antibacterial efficacy against Enterococcus faecalis after root canal irrigation using sodium hypochlorite (NaOCl) combined with chlorhexidine (CHX) with XP-endo Finisher compared to irrigation using sodium hypochlorite with chlorhexidine without XP-endo Finisher.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/02/2022, The Biomedical Research Ethics Committee (BMREC) of Damascus University (Damascus University, Damascus, -, Syria; +963 1133923482; ap.srd@damascusuniversity.edu.sy), ref: DN-210224-185

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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

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
Patients with necrotic pulp

Interventions
Root canal treatment. The study samples (both clinical and laboratory) were divided into six groups: Groups 1 and 2: Irrigation was performed using 5.25% sodium hypochlorite with and without the XP-endo Finisher, respectively. Groups 3 and 4: Irrigation was performed using 5.25% sodium hypochlorite with 2% chlorhexidine, with and without the XP-endo Finisher, respectively. Groups 5 and 6: Irrigation was performed using 5.25% sodium hypochlorite with QMIX, with and without the XP-endo Finisher, respectively.

The randomization process was performed using sealed opaque envelopes managed by an independent party.

Intervention Type
Other

Primary outcome measure
To compare the bacterial count before and after clinical root canal preparation using three final irrigation protocols:
1. Sodium hypochlorite (NaOCl) alone
2. Sodium hypochlorite combined with chlorhexidine (CHX)
3. Sodium hypochlorite combined with QMiX

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
14/03/2021

Completion date
14/03/2025

Eligibility

Key inclusion criteria
1. Patients medically free from any systemic diseases
2. Patients between the age group of 20 and 40 years old
3. Absence of preoperative pain

4. Necrotic cases only
5. Presence of periapical radiolucency 1-5 mm in diameter
6. No antibiotics in the past three months

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
40 Years

Sex
Both

Target number of participants
6 groups (10 teeth in each group)

Total final enrolment
60

Key exclusion criteria
1. Teeth with symptomatic irreversible pulpitis
2. Teeth with open apices
3. Consumption of any type of antibiotics in the past three months
4. Systemic diseases
5. Pregnant and lactating females

Date of first enrolment
01/01/2022

Date of final enrolment
01/01/2023

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
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Sponsor information

Organisation
Damascus University

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University/education

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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
01/05/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are/will be available upon request from Prof. Dr Kinda Layous (kinda.layous@damascusuniversity.edu.sy). All of the patients' data will be available upon request. Consent was obtained from the participants.

IPD sharing plan summary
Available on request