ISRCTN34453184 https://doi.org/10.1186/ISRCTN34453184

Testing of iodine solution to fight bacteria in unsuccessfully treated root canals

Submission date 12/04/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 18/04/2024	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 12/09/2025	**Condition category** Oral Health	[_] Individual participant data

Plain English summary of protocol

Background and study aims

Oral inflammatory diseases encompass a wide range of conditions, particularly apical periodontitis. This type of infection is caused by bacterial biofilm communities adhering to canal walls. Effective management through root canal therapy focuses on eradicating existing infections and preventing bacterial re-infection of the pulp space and surrounding tissues. Success in treatment relies heavily on understanding the microbiological characteristics of apical periodontitis and implementing thorough cleaning, shaping, and irrigation techniques to reduce bacterial load within the root canal system.

The study aims to enhance our understanding of the importance of chemomechanical preparation in endodontic treatment specifically the final irrigation phase. Consequently, maximize the treatment outcomes quality, oral health and patient satisfaction.

Who can participate?

This investigation included patients aged between 18 and 65 years who were referred to the Endodontic Department during the study period because of the presence of apical lesions. The patients also should have signs of asymptomatic periapical periodontitis such as minor percussion pain, or large untreated caries or fractures of the root/crown on one or more maxillary or mandibular anterior (central, lateral and premolar). These patients were radiographed to ensure the existence of periapical lesions <5*5mm.

What does the study involve?

The applied treatments included first Sodium hypochlorite (NaOCl) then the Iodine-Potassium Iodide (IKI) Solution. Two concentrations of IKI were used: 2% and 5%. In the control group, only Sodium hypochlorite (No IKI Solution) was applied.

All samples underwent immediate processing in a specialized laboratory within one hour of collection. The samples were plated onto nutrient agar plates and incubated for 48h at 37°C in aerobic conditions, followed by counting colonies. Monitor of the healing of apical periodontitis radiographically for 12 months.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?
The research was performed in the Endodontic Department at Damascus University, Syria

When is the study starting and how long is it expected to run for?
January 2022 to August 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Meerna SARKEES
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SR23001648

Study information

Scientific Title
Evaluation of the efficacy of iodine potassium iodide IKI irrigating solution in endodontic treatment (in-vivo bacteriologic and radiographic study)

Study objectives
Iodine potassium iodide has an antibacterial effect makes it suitable as a final irrigation solution in the single-visit treatment of teeth with periapical lesions

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/01/2022, The Biomedical Research Ethics Committee (BMREC) of Damascus University (Damascus University, Mazzeh Highway, Damascus, -, Syria; +963 1133923192; sdg@damascusuniversity.edu.sy), ref: DN-290122-18

Study design
Single-centre interventional double-blinded randomized parallel clinical trial

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Single-rooted teeth with periapical lesions

Interventions
The applied treatments included first Sodium hypochlorite (NaOCl) then the Iodine-Potassium Iodide (IKI) Solution. Two concentrations of IKI were used: 2% and 5%. In the control group, only Sodium hypochlorite (No IKI Solution) was applied.
Teeth were allocated, using the simple randomization method, into three groups at a ratio of 1:1:1 depending on the IKI utilized concentration. Patients were asked to randomly select an envelope from a batch of 15 opaque, sealed envelopes per study group, each containing cards with varying final irrigation solutions.

Intervention Type
Other

Primary outcome(s)
Bacterial count was determined by culturing the samples on nutrient agar plates for 48 h at 37°C in aerobic conditions, followed by counting colonies

Key secondary outcome(s))
Monitor the healing of apical periodontitis radiographically for 12 months

Completion date
31/08/2024

Eligibility

Key inclusion criteria

1. Age between 18 and 65 years
2. Patients were referred to the Endodontic Department with the presence of apical lesions.
3. The patients with signs of asymptomatic periapical periodontitis such as minor percussion pain, or large untreated caries or fractures of the root/crown on one or more maxillary or mandibular anterior (central, lateral and premolar).
4. Periapical lesions <5*5mm which were verifier radiographed.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
90

Key exclusion criteria
1. Presence of systemic diseases that compromised general immune status
2. Pregnant females
3. Patients with preoperative anxiety
4. Patients who received antibiotic therapy within the past 3 months
5. Open-apex teeth
6. Teeth with multicanals
7. Internal or external resorptions
8. Patients with advanced periodontitis (more than 5mm periodontal attachment and bone loss)
9. Teeth that were unsuitable for single-visit treatment, containing moist canals with exudation or pus

Date of first enrolment
01/05/2022

Date of final enrolment
03/08/2023

Locations

Countries of recruitment

Syria

Study participating centre
Damascus University
Department of Endodontics
Faculty of Dentistry
Fayez Mansour Street
Damascus
Syria
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Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
Other

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 (mirna2.sarkis@damascusuniversity.edu.sy)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2025	12/09/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Protocol file	18/04/2024	No	No