

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

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| Submission date 12/04/2024 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 18/04/2024 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 18/04/2024 | Condition category Oral Health | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

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?

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Contact information

Type(s)

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

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

Secondary study design

Randomised parallel trial

Study setting(s)

Dental clinic

Study type(s)

Treatment, Efficacy

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

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

Secondary outcome measures

Monitor the healing of apical periodontitis radiographically for 12 months

Overall study start date

29/01/2022

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 verified radiographed.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

90

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

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Sponsor information

Organisation

Damascus University

Sponsor details

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Sponsor type

University/education

Website

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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 high-impact peer-reviewed journal

Intention to publish date
31/08/2024

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? |
|-------------------------------|---------|--------------|------------|----------------|-----------------|
| Protocol file | | | 18/04/2024 | No | No |