

Cover Page

Study Title:

**Antibacterial effectiveness of Frankincense-based herbal irrigant against
endodontic microflora using realtime PCR- a randomized clinical trial**

Brief Title: Frankincense Versus Sodium Hypochlorite for Root Canal Disinfection

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INFORMATION SHEET

Study Title:

Antibacterial effectiveness of Frankincense-based herbal irrigant against endodontic microflora using realtime PCR- a randomized clinical trial

Invitation

You are being invited to consider taking part in the research study titled “Antibacterial efficacy of Frankincense-based herbal irrigant against endodontic microflora using Realtime PCR- a clinical study”

This project is being undertaken by Dr Marwa AlShukaili, Dr NoorAlhuda AlBahrani, and Dr Triveni Mohan Nalawade (Research Supervisor).

Before you decide whether or not you wish to take part, it is important for you to understand why this research is being done and what it will involve. Please take time to read this information carefully and discuss it with others if you wish. If there is anything unclear or if you would like more information, please feel free to ask.

Aims of the Research

The aim of this study is to evaluate the antibacterial efficacy of a Frankincense-based herbal irrigant against endodontic microflora (bacteria inside infected root canals) using real-time PCR technology.

The research may help to understand whether Frankincense can serve as an effective natural alternative to chemical irrigants in root canal treatment, potentially reducing bacterial load and improving treatment outcomes.

Participation

Your participation in this study is entirely voluntary. If you decide to take part, you will be asked to sign an informed consent form.

You are free to ask questions at any stage of the study and you may withdraw at any time without giving any reason. If you withdraw, any data related to you will be systematically destroyed. Every possible effort will be made to maintain confidentiality and protect the identity of all participants.

Procedures

If you agree to participate, you will be a patient requiring root canal treatment due to an infected tooth. During your standard root canal procedure, the following additional research steps will be performed:

1. **Before irrigation:** A small sample of the bacteria (endodontic microflora) inside your root canal will be collected using a sterile paper point.
2. **Irrigation:** Your root canal will be irrigated with the Frankincense-based herbal irrigant as part of the treatment.

3. **After irrigation:** A second bacterial sample will be collected from the same root canal.
4. **Laboratory analysis:** Both samples will be analyzed using real-time PCR (a highly sensitive DNA-based technique) to measure the reduction in bacterial counts.

Your participation will involve only the duration of your root canal appointment. No additional visits are required beyond your standard dental care.

Benefits

You may benefit from the antibacterial action of the Frankincense-based irrigant during your root canal treatment. Your participation will contribute to scientific research on natural alternatives for endodontic disinfection. However, individual benefits cannot be guaranteed beyond standard treatment outcomes.

The study results will be shared with participants as well as presented at conferences or published in scientific journals.

Risks Involved

The Frankincense-based herbal irrigant is generally considered safe and has no known major side effects when used inside root canals. Some individuals may have rare allergic reactions to plant-based products. If you have a known allergy to frankincense or any related botanical substances, you should not participate.

Standard root canal procedures carry minimal risks such as mild post-treatment discomfort, which is unrelated to the research irrigant.

If any discomfort or unexpected reaction occurs, please inform the principal investigator or the research supervisor immediately.

Use of Collected Information

All information collected will be kept confidential. Data will be coded so that participants cannot be identified. Results may be published or presented in an anonymous form. Access will be limited to the research team only.

Access to information

Every possible effort will be made to hide the identities of the people during and after study. Data collected and stored in secure password protected disks along with online cloud storage and data will be coded and not identifiable anyway with the participants. Data will be accessed by researcher and supervisor for analysis. After completion of the study the data will be deleted from all sources.

Funding and Organisation

This study is funded by MOHERi under Block funding Cycle 3- Graduate Research Grant

Contact Information

For concerns or further information, please contact:

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For complaints regarding the research, contact:

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CONSENT FORM

Title of Project: Antibacterial effectiveness of Frankinscence-based herbal irrigant against endodontic microflora using realtime PCR- a randomized clinical trial

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Please write your initials within the box if you agree with the statements below:

1. I confirm that I have read and understood the information sheet dated (version no 1..) for the above study, have had the opportunity to consider the information, ask questions and have had a reasoned explanation. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my treatment or care being affected. In the event of withdrawal, and where it is possible, relevant data will also be withdrawn ☐
3. I understand that relevant sections of my dental records may be accessed by individuals from the research team, from regulatory authorities or from the college where I am receiving treatment. I give permission for these individuals to have access to my records. ☐
4. I understand that the information collected about me can be shared by my treating dentist(part of research team) and may be used to support other research in the future and may be shared anonymously with other researchers. ☐
5. I understand that the information held and maintained by the research team is only available to the researcher or ODC may be used to help contact me or provide information about my dental health status). ☐
6. I agree to take part in this study ☐

Name of participant

Date

Signature

Name of person seeking consent

Date

Signature

