Official title- The effects of natural enzyme containing mouthwash in wound healing after surgical removal of impacted mandibular third molar

NCT Number- Not yet assigned

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RESEARCH ETHICS COMMITTEE (HUMAN)- JEPeM USM
UNIVERSITI SAINS MALAYSIA

TEMPLATE OF PARTICIPANT INFORMATION SHEET AND CONSENT FORM

(RESEARCH PROJECT)

The Participant Infomation and Consent Form used in the Research Project must be according to these information formats. However, statements and phrases used only as a guide.

- Topic of the Research
- Introduction
- Purpose of the Study
- Participants Criteria
- Study Procedures
- Risks
- Reporting Health Experiences
- Participation in the Study
- Possible Benefits
- Questions
- Confidentiality
- Signatures

As an **EXAMPLE**, please refer to the attached Participant Infomation Sheet and Consent Form.

1. **ATTACHMENT B- The effects of natural enzyme containing mouthwash in wound healing after surgical removal of impacted mandibular third molar.**

2. **ATTACHMENT S (Participant Information and Consent Form)**

3. **ATTACHMENT P (Participant's Material Publication Consent Form)**

Information for researchers**:** This template serves only as an example for you to build your own Informed Consent form that suits the need and specificity of your research. Yellow parts in this template should be replaced with specific information related to your studies, or serve as an explanation to you. Before submitting to the JEPeM-USM Secretariat, please make sure all the yellow parts are replaced with specific information of your research.

ATTACHMENT B

RESEARCH INFORMATION

Research Title: **The effects of natural enzyme containing mouthwash in wound healing after surgical removal of impacted mandibular third molar.**

Name of main and co-researcher (Investigators):

1. **Dr. Nabeel Al Huq Bin Reza**
2. **Dr. Marzuki Omar (MDC 2795)**
3. **Assoc. Prof. Dr. Akram Hassan (MDC 2290)**
4. **Dr. Muhammad Syahir (MDC 10273)**

INTRODUCTION

You are invited to take part voluntarily in a research [interventional research]. This research is about assessing your healing status after extraction using a mouthwash that contains natural enzymes.

It is important that you read and understand this research information before agreeing to participate in this study. You will receive a copy of this form to keep for your records if you agree to participate.

Your participation in this study is expected to last for 1 week from the date of participation. The study is estimated to involve up to 58 participants.

PURPOSE OF THE STUDY

The purpose of this study is to determine the healing status after extraction of impacted mandibular 3rd molar using a mouthwash containing natural enzymes compared to non-enzyme containing mouthwash.

PARTICIPANTS CRITERIA

The research team members will discussed your eligibility to participate in this study. It is important that you are completely truthful with the staff including your health history [if relevant ONLY].

This study will include: Individuals over 18 years of age who require extraction of impacted 3rd molar of mandible with bony impaction, absence of acute infection in the affected mandibular third molar, absence of deep caries in adjacent teeth, no known medical disease and drug allergy.

This study will not incude: Individuals with soft tissue impaction only, active smokers, pregnant women and people with mental disabilities.

STUDY PROCEDURES

1. Participants will be assigned to their respective groups randomly before surgery.

2. Clinical procedures will be performed on patients according to the similar standards for each patient which includes disinfection, application of local anesthesia, irrigation, incision, extraction, socket curettage and suturing.

3. After the completion of the surgery, the patient will be given instructions on the procedure of using mouthwash regularly and taking analgesics. Follow-up will be done after 1 week. The clinical research assistant will explain the instructions to the patients and obtain consent in Bahasa Malaysia.

4. At the follow-up appoinment, two blinded examiners will assess the wound healing, pain score and the patient's mouth opening.

5. Within this 1 week, patients will be required to keep a record of their pain score and the number of analgesics taken daily at a specific time in the manual log provided. Patients will also be asked to set reminders on their phones.

6. The study staff will contact the patients regularly via WhatsApp to give reminders.

7. The duration of the first visit that is the day on which the sugery will take place will depend entirely on factors like type and position of impaction, surgeon's experience, tooth morphology and root anatomy, patient factors like mouth opening, anxiety level, cooperation etc. and will usually take around 45 minutes for completion. The duration of the follow-up visit will be around 30 minutes. This is standard for each patient. The total duration of involvement of each patient will be 8 days starting from the day of the surgery till the 7th post-operative day that is the day for follow-up visit

RISKS

Minimal risk is expected from this study. Oral7® Mouthwash is generally considered safe when used as directed. However, as with any product, there are potential risks or side effects. Some users may be allergic to one or more of the ingredients in the mouthwash which can cause mild symptoms such as itching, redness and swelling.

REPORTING HEALTH EXPERIENCES

Please contact, at any time, the following researcher if you experience any health problem either directly or indirectly related to this study.
Dr. Marzuki Omar [MMC Registration No. 2795] at 0139223998 as soon as possible.

PARTICIPATION IN THE STUDY

Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop your participation in the study at anytime, without any penalty or loss of benefits to which you are otherwise entitled. Your participation also may be stopped by the research team without your consent if in any form you have violated the study eligibility criteria. The research team member will discussed with you if the matter arises.

POSSIBLE BENEFITS [Benefit to Individual, Community, University]

This study procedure will be provided to you at no cost. The findings of this study can benefit the community by providing evidence on the beneficial effects of natural enzymes containing mouthwash for wound healing after extraction of impacted 3rd molar of mandible. This will result in an improvement in oral health in general.

Result of the Study

Once the study is completed and the data has been analyzed, you will be offered a summary of the overall feedback and findings. The results will be shared in simple, understandable language and will not include any personal or identifying information. If you wish to receive a copy of the study results, you may inform the study team during your participation or contact us later.

QUESTIONS

If you have any question about this study or your rights, please contact;

Dr. Marzuki Omar, MDC: 2795
Oral and Maxillofacial Clinic
School of Dental Sciences
USM Health Campus
0139223998

If you have any questions regarding the Ethical Approval or any issue / problem related to this study, please contact;

Mr. Mohd Bazlan Hafidz Mukrim
Secretary of Human Research Ethics Committee USM
Division of Research & Innovation (R&I)
USM Health Campus
Tel. No. : 09-767 2354 / 09-767 2362
Email : bazlan@usm.my

OR

Miss Nor Amira Khurshid Ahmed
Secretariat of Human Research Ethics Committee USM
Research Creativity & Management Office (RCMO)
USM Main Campus, Penang
Tel. No. : 04-6536537
Email : noramira@usm.my

CONFIDENTIALITY

Your information will be kept confidential by the researchers and will not be made publicly available unless disclosure is required by law.

Data obtained from this study that does not identify you individually will be published for knowledge purposes.

Your original records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying the study procedures and/or data. Your information may be held and processed on a computer. Only research team members are authorized to access your information.

By signing this consent form, you authorize the record review, information storage and data process described above.

SIGNATURES

To be entered into the study, you or a legal representative must sign and data the signature page [ATTACHMENT S or ATTACHMENT P]

ATTACHMENT S

Subject Information and Consent Form
(Signature Page)

Research Title: **The effects of natural enzyme containing mouthwash in wound healing after surgical removal of impacted mandibular third molar.**

Researcher's Name: **Dr. Nabeel Al Huq Bin Reza**

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form **including any information regarding the risk in this study** and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at anytime.
- I have received a copy of this Participant Information and Consent Form to keep for myself.

_____
Participant Name

_____
Participant I.C No

_____ _____
Signature of Participant or Legal Representative **Date** (dd/MM/yy)

_____
Name of Individual
Conducting Consent Discussion

_____ _____
Signature of Individual **Date** (dd/MM/yy)
Conducting Consent Discussion

_____ _____
Name & Signature of Witness **Date** (dd/MM/yy)

Note: i) All participants who are involved in this study will not be covered by insurance.

ATTACHMENT P

Participant's Material Publication Consent Form
Signature Page

Research Title: **The effects of natural enzyme containing mouthwash in wound healing after surgical removal of impacted mandibular third molar.**

Researcher's Name: **Dr. Nabeel Al Huq Bin Reza**

To become a part this study, you or your legal representative must sign this page.

By signing this page, I am confirming the following:

- I understood that my name will not appear on the materials published and there have been efforts to make sure that the privacy of my name is kept confidential, although the confidentiality is not completely guaranteed due to unexpected circumstances.
- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.
- I have been offered the opportunity to read the manuscript and to see all materials in which I am included, but have waived my right to do so.
- All the published materials will be shared among the medical practitioners, scientists and journalists worldwide.
- The materials will also be used in local publications, book publications and accessed by many local and international doctors worldwide.
- I hereby agree and allow the materials to be used in other publications required by other publishers with these conditions:
- The materials will not be used as advertisement purposes nor as packaging materials.
- The materials will not be used out of context – i.e.: Sample pictures will not be used in an article which is unrelated subject to the picture.

_____

Participant Name

_____ _____ _____

Participant I.C. No. **Participant's Signature** **Date** (dd/MM/yy)

_____ _____

Name and Signature of Individual **Date** (dd/MM/yy)
Conducting Consent Discussion

Note: i) All participants who are involved in this study will not be covered by insurance.