REC 4 / 2020/BM Pind. 2(2020)

Research Ethics Committee
Research Management Centre
Universiti Teknologi MARA
40450 SHAH ALAM
Tel: 03-5544-8069, Faks: 03-5544-2096/2767

Subject Information Sheet

Research Title

The effect of adjunctive triple antibiotic paste in deep periodontal pocket management: A comprehensive investigation of clinical, microbiological, and immunological outcomes through randomised controlled trial

Introduction of Research

Periodontitis is usually initially treated by non-surgical periodontal therapy, including scaling, root debridement , oral hygiene reinforcement (Keestra et al., 2015), which aims to reduce supra and subgingival biofilm by doing root debridement to stop the disease progression. However, mechanical debridement alone is inadequate to eradicate pathogens due to limited accessibility to deep periodontal pockets (Choi et al., 2020). Thus, systemic antibiotic was introduced in the late 80ies as adjunctive to mechanical instrumentation to maintain the host-defense system by targeting pathogens that is unreachable with mechanical debridement and mouth (Cosgarea et al., 2020). However, there are other issues emerged such as antibiotic resistance microorganisms and the adverse effects. Antibiotic should be avoided in localized infection without a tendency to spread systemically (Gradl et al., 2022). It has been reported that 74.2% of patient has resistant periodontal pathogen to at least one of the most common antimicrobials used in periodontal treatment (Cosgarea et al., 2020). On the contrary, locally administered antibiotics offer benefits such as targeted action at the site, reduced systemic impact, increased patient compliance, and improved pharmacokinetic reaction (Choi et al., 2020). Locally delivered drugs has more likely to achieve high gingival crevicular fluid concentration and reduced risk of adverse drug reaction The drawback of systemically administered antibiotics is unpredictability of patient compliance(Barça et al., 2015) TAP consists of metronidazole, targets anaerobic bacteria. Minocycline is bacteriostatic and acts on gram-positive and gram-negative bacteria. Ciprofloxacin has fast bactericidal action and possess antimicrobial activity against gram-negative bacteria while limiting the action of gram-positive bacteria. However, many anaerobic bacteria have resistance to ciprofloxacin thus metronidazole is added. Combination of these three antibiotics yield higher antimicrobial action and avoid bacterial resistance (Omaia et al., 2019). In conclusion, TAP can be an effective combination by acting on gram-negative, gram-positive, and anaerobic bacteria.

Purpose of Research

1. To investigate and evaluate the effectiveness of Triple Antibiotic Paste (TAP) as an adjunctive treatment modality for deep periodontal pockets Specific Objectives: 1. To compare the changes in clinical parameter following the application of Triple Antibiotic Paste (TAP) compared to non-surgical periodontal therapy alone in deep periodontal pockets. 2. To examine the modulation of local inflammatory markers in periodontal tissues after the application of TAP compared to conventional non-surgical periodontal therapy. 3. To quantify subgingival microbial flora Aggregatibacter actinomycetemcomitans (Aa) and Porphyromonas gingivalis (Pg) following the application of Triple Antibiotic Paste (TAP) in patients with deep periodontal pockets compared to conventional non-surgical periodontal therapy.

Research Procedure
Patients will be randomly allocated into two groups: one receiving Triple Antibiotic Paste (TAP) and the other receiving conventional periodontal therapy. This study will be a double-blind design where both participants and investigators will be unaware of the assigned treatment until the completion of the study. Randomization using computerized system, randomly distributed into 2 groups representing 2 therapeutic groups: a. Scaling + root surface debridement(RSD) + adjunctive Triple Antibiotic Paste (intervention group) b. Scaling + root surface debridement(RSD) + placebo (carrier only) (control group) Treatment protocol allocations will be dispensed in opaque envelope and assigned in Spinel Clinic. All patients will undergo scaling and RSD first before being assigned for adjunctive treatment by a different periodontist. Gingival Crevicular Fluid (200microL) will be taken using sterile paper strip from gingival crevice before treatment and 2 months post treatment for microbiological and immunological testing. Clinical assessment at the same interval.

Participation in Research
Your participation in this research is entirely voluntarily. You may refuse to take part in the study, or you may withdraw yourself from participation in the research at any time without penalty.

Benefit of Research
This study can explore the efficacy of TAP in deep periodontal pocket management as another option as an adjunct. Another benefit is it can develop options for the usage of systemic antibiotics in periodontal management to reduce antibiotic resistance. Furthermore, the usage Triple Antibiotic Paste has not been explored for periodontal management yet.

Research Risk
Risks of participation of the study are allergy to antibiotics, in which can be localized or systemic. In localized allergy, rashes urticaria. In systemic reaction, it can include angioedema, fever, enlarged lymph nodes, shortness of breath, anaphylaxis, arthralgia and organ-tissue damage (Warrington et al., 2018).

Confidentiality
Your information will be kept confidential by the investigators and will not be made public unless disclosure is required by law. By signing this consent form**, you will authorize the review of records, analysis and use of the data arising from this research. For any enquiries about this research or you rights, please contact Dr Nursafirah 'Izzati binti Idrus at 013-9608480.

Consent Form[1]

To become a subject in the research, you or your legal guardian are required to sign this Consent Form
I herewith confirm that I have met the requirement of age and am capable of acting on behalf of myself / as
2 a legal guardian as follow:
1. I understand the nature and scope of the research being undertaken.
2. I have read and understood all the terms and conditions of my participation in the research.
3. All my questions relating to this research and my participation therein have been answered to my

satisfaction.

4. I voluntarily agree to take part in this research, to follow the study procedures and to provide all necessary information to the investigators as requested.
5. I may at any time choose to withdraw from this research without giving any reason.
6. I have received a copy of the Subjects Information Sheet and Consent Form.
7. Except for damages resulting from negligent or malicious conduct of the researcher(s), I hereby release and discharge UiTM and all participating researchers from all liability associated with, arising out of, or related to my participation. I agree to hold them harmless from any harm or loss that may be incurred by me due to my participation in the research.

Name of Subject/Legally authorized representative (LAR)	Signature
I.C No	Date
Name of Witness[3]	Signature
I.C No	Date
Name of Consent Taker	Signature
I.C No	Date

[1] Original signed copy is to be retained by the Principal Investigator.
[2] Delete whichever is not applicable.
[3] A witness is only required for oral consent.