ISRCTN10241517 https://doi.org/10.1186/ISRCTN10241517

Clinical trial on the effectiveness of virgin coconut oil as an additional treatment for root scaling and debridement

Submission date
01/02/2023

Recruitment status
No longer recruiting

Registration date
17/04/2023

Overall study status
Completed

Last Edited
06/02/2023

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Periodontitis is a serious infection of the gums that can lead to tooth loss and other serious health complications. It can be treated with scaling and root debridement (SRD), which involves scraping away tartar from the teeth and under the gum line, especially to the tooth with deep periodontal pockets. However, there are limitations of this method, where there may be residual bacteria left behind. Therefore, this study aims to look at the effectiveness of virgin coconut oil (VCO) as an addition to root scaling and debridement.

Who can participate?
Patients with periodontitis

What does the study involve?
This study will involve applications of VCO on the deep periodontal pocket area after SRD has taken place. The applications will be done four times, each every week. The outcome of the study will be measured by measuring specific periodontal parameters every 3, 6 and 9 months.

What are the possible benefits and risks of participating?
The benefit of this study is it may show whether VCO is effective or not as an additional treatment for RSD.

Where is the study run from?
University of Technology MARA (UiTM) (Malaysia)

When is the study starting and how long is it expected to run for?
February 2021 to June 2023

Who is funding the study?
University of Technology MARA (UiTM) (Malaysia)

Who is the main contact?
Dr Nur Shahira Azmi, 2021257496@student.uitm.edu.my

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
REC/09/2021 (FB/52)

Study information

Scientific Title
Local delivery of virgin coconut oil as an adjunct to non-surgical periodontal treatment: a randomized clinical trial

Study objectives
1. Does the application of virgin coconut oil subgingivally in periodontal pockets after root surface debridement (RSD) results in significant improvement of bleeding on probing (BOP) among patients with periodontal disease?
2. Does the application of virgin coconut oil subgingivally in periodontal pockets after root surface debridement (RSD) results in significant improvement of probing pocket depth (PPD) among patients with periodontal disease?
3. Does the application of virgin coconut oil subgingivally in periodontal pockets after root surface debridement (RSD) results in a significant improvement of clinical attachment level (CAL) among patients with periodontal disease?

4. Does the application of virgin coconut oil subgingivally in periodontal pockets after root surface debridement (RSD) results in significant improvement of plaque index (PI) among patients with periodontal disease?
5. Does the application of virgin coconut oil subgingivally in periodontal pockets after root surface debridement (RSD) results in significant improvement of the gingival index (GI) among patients with periodontal disease?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/01/2022, UiTM Research Ethics Committee (Aras 3, Bangunan Wawasan, 40450, Shah Alam, Selangor, Malaysia; +60 (0)3 55448069; recsecretariat@uitm.edu.my), ref: REC/09 /2021(FB/52)

Study design
Single-centre blinded randomized clinical trial study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Generalized periodontitis

Interventions
Initially, the patient will be screened for eligibility to be involved in the study by one researcher (Researcher A). Researcher A also will be the one taking the baseline records, doing oral hygiene education and instructions and also full mouth scaling and root debridement.

Researcher B will be doing randomization of the involved subjects into a placebo or control group via a computer-generated random sequence. The random allocation sequences will be concealed in a sequential sealed opaque envelope and will be open only on the day of intervention applications by dental nurses. Researcher A will be blinded to these allocation sequences.

The intervention (either subgingival applications of distilled water in the control group or virgin coconut oil in the test group) will be done by Researcher C. The interventions will be applied using a blunt soft Intra Vascular cannular tip (22 Gauge), guided by an acrylic stent with marking

on deep pockets. The applications of either placebo or VCO will be done on day 1 after full mouth scaling and root debridement, followed by another application after day 7, day 14 and day 21.
Follow-up visits for the assessment of periodontal parameters (Bleeding on probing, periodontal pocket depth, clinical attachment loss, plaque index and gingival index) will be done by researcher A at 3 months, 6 months and 9 months after treatment.

Intervention Type
Other

Primary outcome measure
Probing pocket depth is measured using a UNC-15 probe to the nearest mm on all six sites of each tooth at baseline, 3 month, 6 months and 9 months.

Secondary outcome measures
1. Clinical attachment loss is measured using a UNC-15 probe to the nearest mm on all six sites of each tooth at baseline, 3 months, 6 months and 9 months.
2. Bleeding on probing will be recorded using the Sulcus Bleeding Index (SBI) at baseline, 3 months, 6 months and 9 months. A Graduated University of North California (UNC-15) probe will be used to probe the pocket up until the bottom on four sites of tooth surfaces (the labial, lingual, mesial and distal sites). Then, the bleeding on probing score will be recorded separately on every four sites according to the sulcus bleeding index score as above. Bleeding on probing score of the individual tooth gain by adding all the bleeding scores on four sites, divided by four and the bleeding score for an individual gain by adding all the individual tooth scores, divided by the total number of teeth present.
3. Plaque index (PLI) recorded using Silness and Loe, 1967 index at baseline, 3 months, 6 months and 9 months. Four surfaces of each tooth will be evaluated (mesiobuccal, mid-buccal, dis-to-buccal and palatal) and given the score accordingly. To get the score for each tooth, all scores from the four areas will be added and divided by four. Finally, to get the individual plaque index, all the tooth scores will be added and divided by the number of teeth present
4. Gingival index recorded using Loe and Sillness 1967 index at baseline, 3 months, 6 months and 9 months. To assess the gingival index score, the qualitative changes of the gingiva soft tissue will be examined by direct vision and gentle probing using the UNC-15 probe up until the gingival crevice only. Each tooth will be evaluated at four sites; buccal, mesial, distal and lingual /palatal, and will be given a score according to the criteria listed. To get the score for an individual tooth, all the scores at the four sites will be added and divided by four. Meanwhile, for an individual score, all gingival index scores for each tooth will be added and divided by the total number of teeth present.

Overall study start date
01/02/2021

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Periodontitis patient with no history of systemic disease
2. Periodontitis patient presents with at least Stage II periodontitis (based on the New 2017 Classification of Periodontal and Peri-Implant Disease and Conditions) with at least 20 teeth

present
3. No history of periodontal and antibiotic therapy within the past 6 months

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
32

Key exclusion criteria
1. Involvement in another clinical trial
2. Allergy or potential allergy to herbal medications.
3. Smoker/alcoholic
4. Completely edentulous individuals
5. Individuals with systemic diseases, such as acquired immune deficiency syndrome, cardiovascular disorders, diabetes, hepatic diseases (including hepatitis B and C) and renal diseases
6. Individuals that reported to have undergone periodontal therapy within the past 6 months
7. Individuals that reported to have used antibiotics, non-steroidal anti-inflammatory drugs and /or steroid use within the past 6 months.
8. Pregnancy or lactating women

Date of first enrolment
12/01/2022

Date of final enrolment
01/03/2023

Locations

Countries of recruitment
Malaysia

Study participating centre
Faculty of Dentistry Uitm Sungai Buloh
Jalan Hospital
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Malaysia
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Sponsor information

Organisation
Universiti Teknologi MARA

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Sponsor type
University/education

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Funder(s)

Funder type
University/education

Funder Name
Universiti Teknologi MARA

Alternative Name(s)
Universiti Teknologi MARA - UiTM, MARA Technological University, Universiti Teknologi MARA (UITM), Universiti Teknologi MARA in Malaysia, Universiti Teknologi MARA MIMI, Universiti Teknologi MARA | Shah Alam, Malaysia | UiTM, Universiti Teknologi MARA, Malaysia, Universiti Teknologi Mara (UiTM), Malaysia, UiTM – Universiti Teknologi MARA, Universiti Teknologi MARA (UiTM) (Klang, Malaysia), UiTM - Universiti Teknologi MARA, Universiti Teknologi MARA Malaysia, , University of Technology MARA, UiTM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Publication and dissemination plan
Planned publications in high-impact peer-reviewed journals.

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date