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The role of Moringa and Acemmanen in accelerating wound healing

Submission date
28/10/2023

Recruitment status
No longer recruiting

Registration date
07/11/2023

Overall study status
Completed

Last Edited
02/11/2023

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
Current research from around the world shows that using Moringa and Acemannan can be safe and beneficial for various health issues. While many plants have been used for their benefits after having a tooth removed, there's not much evidence about how effective Moringa leaf extract and Acemannan are specifically for healing in the upper back of the mouth. Additionally, no previous studies have compared the results of using these substances on one side of the mouth versus the other, both in terms of clinical outcomes and what we can see on X-rays. Most of the research involving people has been systematic and comprehensive, but a few studies have been more local, focusing on either dental implants or healing after tooth extraction.

However, because many studies using these substances locally on animals have shown positive results, we have decided to investigate how Moringa and Acemannan affect the healing process in humans, specifically in the area where a tooth has been removed.

Who can participate?
The participants in this study will be patients from the College of Dental Medicine at Umm Al-Qura University who require the extraction of one posterior maxillary tooth in the right maxilla and one posterior tooth in the left maxilla.

What does the study involve? (for participants)
The study involves placing either Moringa or Acemannan plant extract in the socket after tooth extraction, with one side covered with a collagen membrane and the other side left untreated.

What are the possible benefits and risks of participating?
Possible benefits of this study include the extraction of non-restorable teeth, enhanced healing after extraction, and the potential identification of existing infections through the use of Cone-beam computed tomography (CBCT) scans.

Potential risks associated with the study include complications related to tooth extraction, anesthesia, and medications. These complications may manifest as swelling, pain, infection, bleeding, abscess formation, sensitivity, dry socket, damage to adjacent teeth or fillings, aspiration or swallowing of foreign objects, restricted mouth opening, muscle soreness,

osteomyelitis, root fragments remaining in the jaw, sinus-related issues, bone fractures, gastrointestinal side effect of the medication, anaphylaxis and unexpected reactions. The use of Moringa leaf extract or Acemannan may cause local irritation, including swelling, sloughing, redness, bleeding, inflammation, bone loss, infection, pain, and allergic reactions. Cone-beam computed tomography scans involve minimal risk, primarily associated with exposure to low doses of radiation. Pregnant women will not be included in the study. Alveolar socket bone dimensions measurements and probing pocket depth examinations may result in minor discomfort, pain, bleeding, inflammation, and swelling of the gums. It is important to note that efforts will be made to minimize these risks and ensure the safety and well-being of the participants throughout the study.

Where is the study run from?
Umm Al-Qura dental Teaching Hospital (Saudi Arabia)

When is the study starting and how long is it expected to run for?
December 2022 to June 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Abrar Demyati, akdemyati@uqu.edu.sa

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
Approval No. (HAPO-02-K-012-2022-11-1336)

Study information

Scientific Title

The role of Moringa and Acemmanen in accelerating healing and alveolar socket regeneration after teeth extraction; randomized controlled trial

Study objectives
Utilization of Moringa Leaf Extract or Acemannan with collagen membrane in fresh extraction socket will improve alveolar bone and soft tissue healing during 30 days after the extraction.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/12/2022, Biomedical Research Ethics Committee, Umm Al-Qura University (Alawali, Mecca 24381, Makkah, 21955, Saudi Arabia; +966 125270000; akdemyati@uqu.edu.sa), ref: Approval No. (HAPO-02-K-012-2022-11-1336)

Primary study design
Interventional

Study design
Prospective controlled blind split-mouth randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Healing and alveolar socket regeneration after teeth extraction

Interventions
It will include a total of 15 patients in each group who need extraction of one posterior maxillary tooth in the right maxilla and one posterior tooth in the left maxilla. One group will receive the Moring covered with a collagen membrane on one side and nothing on the other side and the other group will receive Acemannan covered with a collagen membrane on one side and nothing on the other side.

Moringa Leaf / Acemannan extraction and characterization
Samples will be collected from its origin places and will be authenticated at the pharmacognosy department, pharmacy college, Umm Al-Qura University by a botanist. The plants will be extracted with alcohol using the sequential extraction method to extract its active constituents. The filtrate will be collected and evaporated using a rotary evaporator. The sample will be prepared in its stick form to be used in this research.

The total duration of the study is expected to be 12 months. Subject participation is likely to consist of multiple visits for 4 months.

The randomization will be done by means of a preoperative envelope done by a coordinator. The envelop will be opened only by the operator on the time of the surgery to decide which site will be the control and which site will be the test.

Intervention Type
Supplement

Primary outcome(s)
Bucco-palatal width & vertical height of the alveolar ridge measured using Cone beam computed tomography (CBCT) which performed before the tooth and after 3 months following the tooth extractions.

Key secondary outcome(s)
Baseline and follow-up visits. They are as followed : visit 2 (baseline, enrollment, randomization), visit 3 (Follow up (F/U) at 24hr), visit 4 (F/U at the 3rd day), visit 5 (F/U at the 10th day) and visit 6 (F/U at 3 months)
1. Socket wound healing will be assessed using Landry, Turnbull, and Howley index (LWHI) measured at baseline and follow-up visits.
2. Changes in PD, CAL, BoP and gingival rescission measured using periodontal probe in addition to clinical examination at baseline and follow-up visits
3. Subject satisfaction will be assessed using a Visual Analogue Scale (VAS) (scored from 0–100) at the baseline and follow-up visits.
4. Complications (swelling, suppuration, pain, infection, etc.) measured using examination kit and clinical examination at baseline and follow-up visits

Completion date
01/06/2024

Eligibility

Key inclusion criteria
1. Subjects must voluntarily sign the informed consent.
2. Subjects must be male or female who are at least 19–50 years of age.
3. Subjects must be able and willing to follow study procedures and instructions.
4. Subjects must have no systemic diseases or any other condition that may affect the bone healing or interfere with the periodontal health.
5. Subjects must have no history of using systemic antibiotics or non-steroidal anti-inflammatory agents during the last 6 months.
6. The same type of tooth should be on both sides, either two anterior or two premolars or two molars.
7. Teeth extractions must be completed successfully at College of Dental Medicine at Umm Al-Qura University (i.e. Department of Oral and Maxillofacial Surgery).
8. No fragment of root should be left in the jaw.
9. Four walls of the tooth socket should be present after extraction.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
19 Years

Upper age limit
50 Years

Sex
All

Total final enrolment
4

Key exclusion criteria
1. Existence of any systemic condition such as uncontrolled diabetes mellitus, cancer, disorders that compromise wound healing, history of radiation therapy of the head and neck area, chronic steroid therapy, intravenous and oral bisphosphonate therapy, bone diseases, immunosuppressive therapy or any other condition that would contraindicate oral surgical treatment.
2. Pregnant or lactating women or who plan to become pregnant during the study.
3. Subjects who have failed to maintain good oral hygiene and plaque control.
4. Allergy or hypersensitivity to any products used throughout the study (Moringa extract or Acemannan or collagen membrane).
5. Presence of ≥3 mm of vertical loss of the buccal bone in relation to the palatal wall.
6. Subjects with active periodontitis.
7. Presence of acute dentoalveolar infections in the teeth involved in the study.
8. Subjects who are heavy smokers (defined as >10 cigarettes per day or >1 cigar per day) or chew tobacco or use any tobacco product within 3 months prior to enrollment.
9. Subjects who have para-functional habits.
10. Subjects with lesions, abnormalities, or variations in anatomical landmarks, especially in the sinus.
11. Subjects with circumstances, in the opinion of the investigator, which would prevent completion of study participation, such as history of noncompliance or unreliability.

Date of first enrolment
07/06/2023

Date of final enrolment
30/03/2024

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Umm Al-Qura dental Teaching Hospital
Alawali, Mecca 24381
Makkah
Saudi Arabia
21955

Sponsor information

Organisation
Umm al-Qura University

ROR
https://ror.org/01xjqrm90

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during/or analysed during the current study will be available upon request from the primary investigator: Abrar Demyati, akdemyati@uqu.edu.sa

IPD sharing plan summary
Available on request