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The effectiveness of aloe vera extract on socket healing after dental extraction

Submission date
15/04/2022

Recruitment status
No longer recruiting

Registration date
22/04/2022

Overall study status
Completed

Last Edited
22/04/2022

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Extraction is one of the most common procedures in the dental clinic and sometimes results in complications such as dry socket, infection, and bleeding. Medicines, especially antibiotics, are often prescribed to prevent these complications, which may cause damage at the level of the individual and society in general due to the development of bacterial resistance. Even after effective healing of the extraction site, absorption must occur at the alveolar margin later, which makes dental replacement procedures more difficult in the future, and many procedures and materials have been used to reduce this absorption, and each of them has its advantages and disadvantages. The use of medicinal plants in the medical field is not new, especially the aloe vera plant, because of its well-known properties in healing wounds in addition to its anti-bacterial and anti-inflammatory effects. In addition, its effectiveness at inducing bone healing has been suggested in several studies, but no emphasis has been placed on its ability to reduce socket resorption after tooth extraction. The aim of this study is to assess the effectiveness of aloe vera extract on socket healing after dental extraction.

Who can participate?
Patients aged 18-45 years with premolars (the teeth are between the canine front teeth and the molars) that require extraction

What does the study involve?
Participants will be randomly divided into two groups. For the first group aloe vera powder will be applied after extraction with gel foam and an X-shaped suture will be made. For the second group the tooth will be extracted without applying any material and only gel foam will be placed and an X-shaped suture will be made. Pain will be evaluated 2 hours after the extraction and on the third and seventh day, healing will be evaluated on the third and seventh days, and an image will be taken immediately after the extraction and after 4 months in order to assess the dimensions of the alveolar bone.

What are the possible benefits and risks of participating?
Participants will receive oral health care instructions from the beginning of the study, and the

patients can be referred to other departments if they need other oral treatments, and after the end of the study, dental implants can be performed for patients in order to replace the missing tooth in the Oral and Maxillofacial Department.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
April 2019 to December 2022

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Nour al-Halaby
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2986

Study information

Scientific Title
Evaluation of the effectiveness of aloe vera in soft tissue healing and socket preservation after extraction

Study objectives
1. Aloe vera will promote soft tissue healing after extraction
2. Aloe vera will reduce vertical and horizontal alveolar bone resorption after extraction

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 05/08/2019, ethics scientific committee at Damascus University (Mazzeh Street, PO Box 30621, Damascus, Syria; +963(11)339 23223; drsalloum74@hotmail.com), ref: 2986

Study design
Single-center interventional double-blind randomized controlled trial with a split-mouth design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Soft tissue healing and socket preservation after dental extraction

Interventions
After taking the patient's medical history and evaluating their general health according to the research conditions, written consent will be taken on the content and terms of the research, and research groups will be allocated by coin-flipping. The study sample will be randomly divided into two groups: group A (aloe vera group, n = 20) and group B (control group, n = 20). All extractions will be performed by one surgeon to standardize the surgical trauma. The premolars will be extracted after making sure that they are indicated. Local anaesthesia will be lidocaine 2% with epinephrine 1/80000. In group A, aloe vera powder will be placed with gel foam with an X suture to stabilize the material inside. In group B gel foam will be placed with the X suture to standardize procedures on both sides. A sterile gauze will be placed and the patient will be asked to keep it for 1 hour to help the powder set.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Pain measured using a visual analogue scale (VAS) 2 hours after extraction and on the third and seventh day
2. Healing assessed by the Landry et al. healing index on the third and seventh day
3. The dimensions of the alveolar bone assessed by cone-beam computed tomography (CBCT) immediately after extraction and after 4 months

Key secondary outcome(s))
The dimensions of the alveolar bone assessed by CBCT after 4 months

Completion date
15/12/2022

Eligibility

Key inclusion criteria

1. Patients who accepted participation with written consent
2. Adults aged 18-45 years
3. Patients need bilateral upper or lower premolars extraction

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
All

Key exclusion criteria
1. Heavy smokers
2. Pregnant
3. Uncontrolled diabetes patients
4. Presence of cysts or tumors at the extraction site
5. Patients with advanced periodontitis
6. Patients who are allergic to the plants of the Liliaceae family

Date of first enrolment
15/10/2019

Date of final enrolment
15/10/2022

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Oral and Maxillofacial Surgery Department
Faculty of Dentistry
Mazzeh Street
PO Box 30621
Damascus

Syria
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Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Individual participant data (IPD) sharing plan
The original data, along with the codebook and analysis scripts, will be stored in a non-publicly available repository at Damascus University. The data will consist of csv sheets with the data of the patients and R analysis scripts. The dataset will be called dataset and the dataset generated by the research, including also preprints and technical reports, will be called dataverse. The dataverse corresponding to this investigation will receive a digital object identifier (DOI). The citation has seven components. Five are human-readable: the author(s), title, year, data repository (or distributor), and version number. Two components are machine-readable: the DOI and the universal numeric fingerprint (UNF). The data generated will be de-identified using R's

randomizeR package, removing all personal information. The naming convention for the archives will be date in yyyymmdd-version-identifier.extension format. The use of spaces will be avoided, being replaced by -. The original anonymized data will be published in the Mendeley data repository with restricted access once the data cleaning and exploratory analysis stage is completed. The data will be made public at the time of sending the final report to a peer-reviewed journal, with its DOI corresponding to the data associated with the research. The data will be embargoed until the final report is accepted, at which time it will become publicly available. No access restrictions will be applied to the data once the final project report has been accepted.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			22/04/2022	No	Yes
Protocol file			22/04/2022	No	No