ISRCTN58370471 https://doi.org/10.1186/ISRCTN58370471

Effects of aloe vera hydrogel on healing of soft tissue of the mouth

Submission date
02/02/2021

Recruitment status
No longer recruiting

Registration date
16/02/2021

Overall study status
Completed

Last Edited
16/02/2021

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
The presence of an adequate amount of attached gum is important to prevent the development of gingivitis (inflammation of the gums), periodontal diseases (gum diseases), and tooth loss. Many techniques have been developed to increase the width of the attached gum and to combat gum recession. A surgical process called a free gingival graft is considered the golden standard in treatment. This surgery involves removing a small amount of tissue (the graft) from the roof of the mouth (the donor site) and then attaching this to the gum area being treated (the recipient site) where the gum has receded or is too thin. During the healing process of free gingival graft surgery, patients can experience changes in the dimensions changing of the gum, a lack of color matching between the graft and the recipient site, as well as post-operative pain and irritation. Healing of the donor site takes time and may delay the completion of the surgical procedures

Recent studies have been looking for treatments that address the problems associated with this surgery. The aloe vera plant has anti-inflammatory, anti-fungal properties, and has the ability to accelerate the healing of skin wounds and ulcers. The study team has developed an aloe vera gel suitable for application to the mouth. This study will test the effect of aloe vera gel on healing the free gingival graft and the donor site in terms of pain severity and the speed of healing compared to the natural healing process.

Who can participate?
Adults with a width of attached gingiva less than 2 mm, with otherwise good oral and general health, and who have not had periodontal surgery during the previous six months

What does the study involve?
A free gingival graft was performed for all participants. Participants will be randomly allocated (like a coin toss) to one of two groups. Following the surgery, one of the groups of participants will receive laboratory-manufactured aloe vera hydrogel injected by syringe twice daily for 10 days into the donor site and the recipient site. This treatment will be given at the faculty of Pharmacy in Damascus University. The other group of participants will have no additional treatment and undergo natural healing that will be monitored.

Healing of the site where the tissue was harvested and the site of the graft will be monitored for a 3 month period in all participants by measuring the pain severity in both areas, the speed of epithelial (the mechanical barrier against infection) formation, gum shrinkage, and evaluation of the scar.

What are the possible benefits and risks of participating?
In both groups, the gum problem will be treated, which improves the participant's ability to apply better oral health care procedures such as brushing. Patients in the study group may have difficulty applying the appropriate amount of hydrogel. Therefore, one of the family members is asked to help with this as the patients may suffer a minor degree of pain during the first and two days after surgery.

Where is the study run from?
Department of Periodontology, Damascus University (Syria)

When is the study starting and how long is it expected to run for?
From December 2018 to March 2021

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Walaa Alawad
info@damascusuniversity.ed.sy

Contact information

Type(s)
Scientific

Contact name
Dr Walaa Alawad

Contact details
Faculty of Dentistry
Damascus University
Damascus
Syria
00000
+963 (0)962975608
wala.alawad@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
2985\ s.m

Study information

Scientific Title
Effect of aloe vera extracted Hydrogel on the healing of free gingival graft and palatal donor site

Study objectives
Aloe vera hydrogel accelerates the healing of the free gingival graft and the donor palatal site more than the normal healing

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/08/2019, The Council of Scientific Research and Graduate Studies at Damascus University (Rami Street, Marjeh, Damascus, Syria; +963 2241684; swadee1979@gmail.com), ref: 3873

Study design
Interventional single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
See additional file ISRCTN58370471_PIS_Arabic_09Feb2021

Health condition(s) or problem(s) studied
Gingival recession, free gingival graft healing

Interventions
Participants will be randomized to either the experimental group or the control group. Randomized using a method of pulling a sheet of 22 sheets, including 1 as a reference to the study sample on 11 sheets and 2 as a reference to the control sample on the remaining 11 sheets.

The experimental group will use aloe vera gel, applied via syringe with special heads to the donor and recipient sites after the free gum graft operation, 0.5 ml twice daily at each site for 10 days.

The control group will have no additional treatment after the free gum graft operation.

Participants will be followed up for 3 months.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
aloe vera hydrogel

Primary outcome measure
1. Graft shrinkage during follow-up periods measured using a computer program that measures graft dimensions through photographs taken at 7, 14, 21, 28, 60, and 90 days

Secondary outcome measures
1. Epithelization measured using examination of epithelial formation at the graft site and donor site with Toluidine blue in the donor and recipient regions at 7, 14, 21, 28, 60, and 90 days
2. Mucosal scar measured using Mucosal Scarring Index at 7, 14, 21, 28, 60, and 90 days
3. Pain in the donor and recipient regions is measured using a visual analog scale (VAS) at 2 h after surgery, and at 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 days
4. Healing in donor site measured using Wound Healing index (by Landry, Turnbull, and Howley) at 7, 15, 21, 28, 60, and 90 days

Overall study start date
01/12/2018

Completion date
01/03/2021

Eligibility

Key inclusion criteria
1. Width of attached gingiva <2 mm in the lower anterior region
2. Thickness of the soft tissue in the dome of the palate >3 mm
3. Aged >18 years
4. Good oral health
5. Good systemic health

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
22

Key exclusion criteria
1. Acute gingival inflammation or periodontitis
2. Uncontrolled plaque accumulation (hairy plaque >1)
3. Patients undergoing current orthodontic treatment
4. Patients with systemic conditions or taking medications that affect the healing of the periorbital tissue
5. Pregnancy and breast-feeding
6. Dental movement in the surgical area
7. Have received surgical dental treatment within the last six months

Date of first enrolment
13/09/2020

Date of final enrolment
28/02/2021

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Department of Periodontology
Mazzah High Way
Damascus
Syria
0000

Sponsor information

Organisation
Damascus University

Sponsor details

Albaramkeh
Damascus
Syria
0000
+9631133923192
info@damascusuniversity.edu.sy

Sponsor type
University/education

Website
http://damasuniv.edu.sy/

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal.

Intention to publish date
01/03/2022

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		09/02/2021	16/02/2021	No	Yes
Participant information sheet		09/02/2021	16/02/2021	No	Yes
Participant information sheet		09/02/2021	16/02/2021	No	Yes