Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating the effects of hyaluronic acid mucoadhesive films with two different concentrations on palatal epithelial wound healing and post-operative discomforts after free gingival graft surgery

Protocol summary

Study aim

To determine the effects of hyaluronic acid (HA) mucoadhesive films with two different concentrations on palatal epithelial wound healing and post-operative discomforts after free gingival graft (FGG) surgery

Design

Clinical trials with a control group, with parallel groups, double-blind, randomized. Patients will randomly divided into three groups using the option of generating random numbers in https://kitset.ir.

Settings and conduct

Patients selected from candidates for FGG surgery referred to the periodontology department of Babol University of Medical Sciences in 1401.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients over the age of 18; 2. Patients who required free gingival graft; 3. Presence of sufficient donor tissue dimensions in the palate (length: 10-15mm, width: 5-8mm, thickness: 1-1.5mm); Exclusion criteria: 1. Systemic diseases and conditions affecting wound healing (such as uncontrolled diabetes, autoimmune diseases, history of alcoholism); 2. Presence of attachment loss (greater than 3mm) in the palatal area of premolars and first maxillary molars; 3. Use of corticosteroids; 4. Use of antibiotics in the past month; 5. Pregnancy or breastfeeding; 6. Smoking.

Intervention groups

Giving sufficient information, taking informed consent, Phase I periodontal therapy, Harvesting free gingival graft, Placing mucoadhesive films containing 0.8% HA (test group1), mucoadhesive films containing 0.2% HA (test group2) and HA free biofilms (control group) in the donor site, stabilizing it by sutures, Covering it with periodontal dressing, Regular evaluation on days 3, 7, 14, 21 and 42 after surgery.

Main outcome variables

If the results are statistically significant, using mucoadhesive biofilms containing HA could be considered as an adjunctive way for accelerating palatal epithelial wound healing and reducing post-operative discomforts of FGG surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100427003813N12**
Registration date: **2022-04-14, 1401/01/25**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-14, 1401/01/25**
Update count: **0**

Registration date

2022-04-14, 1401/01/25

Registrant information

Name

Niloofar Jenabian

Name of organization / entity

Dental Faculty of University of Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 11 1229 1408

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-08, 1401/01/19

Expected recruitment end date

2022-08-08, 1401/05/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of hyaluronic acid mucoadhesive films with two different concentrations on palatal epithelial wound healing and post-operative discomforts after free gingival graft surgery

Public title

Evaluating the effects of hyaluronic acid mucoadhesive films with two different concentrations on palatal epithelial wound healing and post-operative discomforts after free gingival graft surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who required free gingival graft; Presence of sufficient donor tissue dimensions in the palate (length: 10-15 mm, width: 5-8 mm, thickness: 1-1.5 mm).

Exclusion criteria:

Systemic diseases and conditions affecting wound healing (such as uncontrolled diabetes, autoimmune diseases, history of alcoholism); Presence of attachment loss (greater than 3 mm) in the palatal area of premolars and first maxillary molars; Use of corticosteroids; Use of antibiotics in the past month; Pregnancy or breastfeeding; Smoking.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **39**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomly grouping the participants, we will use the option of generating random numbers in https://kitset.ir. Then, according to the random numbers, the first 13 numbers are in the first group, the next 13 numbers are in the second group, and the last 13 numbers are in the third group. Finally, the labeled biofilms (by the pharmacologist) are used in individuals of the all three groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The biofilms containing hyaluronic acid with two different concentrations and the biofilms without hyaluronic acid are labeled with numbers by the pharmacologist and provided for the operator. The operator will be unaware of the type of biofilm used in the patient.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Babol University of Medical Sciences

Street address

Ganj Afrooz Ave.

City

Babol

Province

Mazandaran

Postal code

4717649811

Approval date

2022-02-02, 1400/11/13

Ethics committee reference number

IR.MUBABOL.REC.1400.262

Health conditions studied

1

Description of health condition studied

palatal epithelial wound healing and post-operative discomforts after free gingival graft surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Complete epithelialization of the donor site in palate

Timepoint

3, 7, 14, 21 and 42 days after surgery

Method of measurement

Landry 's healing index

2

Description

Color matching, contour and distortion of the donor site in palate

Timepoint
3, 7, 14, 21 and 42 days after surgery
Method of measurement
Modified Manchester Scar Proforma index

3

Description
Postoperative pain
Timepoint
3, 7, 14 and 21 days after surgery
Method of measurement
Visual analogue scale (VAS)

4

Description
Patient response to thermal stimulus after surgery
Timepoint
3, 7, 14 and 21 days after surgery
Method of measurement
Visual analogue scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: mucoadhesive films containing hyaluronic acid 0.8%
Category
Treatment - Other

2

Description
Intervention group 2 : mucoadhesive films containing hyaluronic acid 0.2%
Category
Treatment - Other

3

Description
Control group: mucoadhesive films without hyaluronic acid
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Periodontics department, School of Dentistry, Babol University of Medical Sciences
Full name of responsible person
Parisa Nabiyi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Niloofar Jenabian
Position
Professor

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available