

# 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)

##### Phone

+98 11 1229 1408

##### Email address

n.jenabian@mubabol.ac.ir

##### 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 Nabiyyi

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Ganj Afrooz Ave.

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+98 919 347 3829

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prs.nby@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Reza Ghadimi

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Ganjafroz Ave.

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rezaghadimi@yahoo.com

**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**

Specialist

**Other areas of specialty/work**

Dentistry

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

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**Position**

Prefessor

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Specialist

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Parisa Nabiyi

**Position**

Postgraduate student of periodontics

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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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