

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Investigating The Effect Of Bromelain Gel Added To Periodontal Pack Compared To Periodontal Pack Alone On The Healing Of Palatal Wound Resulting From Harvesting The Free Gingival Graft On Patients With Keratinized Gingival Width Deficiency Who Are Candidates For Gingival Grafting; A Parallel Clinical Trial Study

#### Protocol summary

##### Study aim

Evaluation the effect of the bromelain Gel on wound healing after free gingival graft

##### Design

Two arm parallel group randomized trial with double-blind postoperative care, outcome assessment and participants. Phase 3 on 28 patients. Block method will be used for randomization.

##### Settings and conduct

A study on the healing of palatal wound after free gingival grafting will be conducted on patients with keratinized gingival width deficiency who are candidates for gingival grafting in Tehran Faculty of Dentistry with two groups with and without the use of bromelain gel. Participants and analyzers Statistics of the type of surgical technique performed in each patient are blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients over 18 years old who need free gingival grafting treatment around teeth or implants, systemically healthy, non-smokers, measuring 10 mm wide and 15 to 20 mm long. Exclusion criteria: presence of periodontal disease, systemic diseases that are contraindications to periodontal surgeries or interfere with tissue repair, pregnancy and breastfeeding.

##### Intervention groups

Control group: for patients in this group, no bromelain gel will be placed on the wound site after surgery, and only the periodontal pack will be placed on the palatal wound area. Intervention group: 1% bromelain gel is placed in the palatal wound area of these patients after surgery, and after applying the gel, a periodontal pack is placed in the palatal wound area.

##### Main outcome variables

The average area of the remaining wound in the palate

area, the amount of bleeding , the amount of color adaptation, the amount of epithelialization, pain and discomfort, Lundry's healing index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231118060098N1**

Registration date: **2024-01-12, 1402/10/22**

Registration timing: **prospective**

Last update: **2024-01-12, 1402/10/22**

Update count: **0**

##### Registration date

2024-01-12, 1402/10/22

##### Registrant information

##### Name

Fateme Godarzi Moghadam

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4279 4000

##### Email address

f-goodarzim@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-03-10, 1402/12/20

##### Expected recruitment end date

2024-09-10, 1403/06/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating The Effect Of Bromelain Gel Added To Periodontal Pack Compared To Periodontal Pack Alone On The Healing Of Palatal Wound Resulting From Harvesting The Free Gingival Graft On Patients With Keratinized Gingival Width Deficiency Who Are Candidates For Gingival Grafting; A Parallel Clinical Trial Study

**Public title**

The effect of pineapple gel on palatal wound healing after gingival graft

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients over 18 years old  
The need for free gingival graft around the tooth or implant  
Systemically healthy  
Non-smokers  
Graft dimensions 10 mm wide and 15 to 20 mm long

**Exclusion criteria:**

Active gag reflex  
Presence of periodontal disease  
Lack of sensation  
Mobility and occlusal trauma  
Missing canine teeth up to maxillary first molar  
Additional forces including mechanical forces from orthodontics and traumatic occlusion  
Systemic diseases that are contraindications for periodontal surgeries or have interactions by tissue repair  
Pregnancy and breastfeeding

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **28**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The samples are randomly divided into two groups using balance block randomization (size = 4). For this purpose, the allocation method in each of the blocks is determined using Excel software in such a way that at least 2 samples of any intervention are in each block. The randomization process is carried out by the study methodology consultant. The type of allocation after randomization is noted in the envelope with numbers 1 to 28 for each sample. When conducting the study, the operator opens the envelopes in order and aware of the

type of sample's allocation at the time of intervention.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

People entered in the study, knowing that they are participating in a research study, are blinded to the allocation to the desired treatment group, and the statistical analyzer is blinded to the type of surgical technique performed in each patient. Both groups receive periodontal packs with the same color, taste and shape, so the patient does not know the presence or absence of gel under the pack.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Dental school; not reaching Hakim highway; At the end of North Kargar street

**City**

Tehran

**Province**

Tehran

**Postal code**

1439955991

**Approval date**

2023-10-21, 1402/07/29

**Ethics committee reference number**

IR.TUMS.DENTISTRY.REC.1402.069

**Health conditions studied**

1

**Description of health condition studied**

Palate wound

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

The average area of the remaining wound in the palate

**Timepoint**

Days 7, 14, 21 and 28 after surgery

**Method of measurement**

Image J computer program to check the area of the remaining wound

## 2

### **Description**

The amount of bleeding after surgery

### **Timepoint**

The first 3 days after surgery

### **Method of measurement**

Questionnaire and observation

## 3

### **Description**

The degree of color matching

### **Timepoint**

Days 7, 14, 21 and 28 after surgery

### **Method of measurement**

Adobe Photoshop CS3 computer program to check Brightness parameters

## 4

### **Description**

The amount of epithelialization

### **Timepoint**

Days 7, 14, 21 and 28 after surgery

### **Method of measurement**

Using 3% H2O2 and observing oxygen bubbles

## 5

### **Description**

Average index of pain and discomfort

### **Timepoint**

Days 7, 14, 21 and 28 after surgery

### **Method of measurement**

Questionnaire and VAS chart

## 6

### **Description**

Lundry's healing index next

### **Timepoint**

Days 7, 14, 21 and 28 after surgery

### **Method of measurement**

Direct touch and examination by a specialist

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: In this study free gingival graft surgery is performed by removing the graft from the palate area, 1% bromelain gel, a polymer gel made from mixing biocompatible polymer and water (at high temperature) and a microbial protector that is allowed to

be used in the mouth (to prevent microbial contamination), with the active ingredient of the study that It is bromelain powder. After surgery, 1% bromelain gel is placed on the wound area for patients in this group, and after applying the gel, a periodontal pack is placed on the palatal wound area. The gel is applied on the area on the day of surgery and two days later.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Free gingival graft surgery is performed by removing the graft from the palate area. After the surgery, no gel is placed on the wound area of the patients in this group, and only periodontal pack is placed on the area of the palate wound.

#### **Category**

Treatment - Surgery

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Faculty of Dentistry, Tehran University of Medical Sciences

##### **Full name of responsible person**

Fateme Godarzi Moghadam

##### **Street address**

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##### **Phone**

+98 21 8670 5503

##### **Email**

fateme.godarzii1998@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Ali Akbari Sari

##### **Street address**

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##### **Province**

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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**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Fateme Godarzi Moghadam

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

Resident

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## Person responsible for updating data

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Tehran University of Medical Sciences

**Full name of responsible person**

Fateme Godarzi Moghadam

**Position**

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**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