

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

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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	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
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	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
Age From 18 years old Gender Both Phase 3 Groups that have been masked - Participant - Outcome assessor - Data analyser	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
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	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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali Akbari Sari

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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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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