

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating the efficacy of Bromelain on donor wound healing after free gingival surgery

Protocol summary

2015-03-15, 1393/12/24

Summary

The main purpose of the study is determining the efficacy of Bromelain on donor wound healing after free gingival surgery that will do according to a randomized , double blind and placebo-controlled study. Study population: Individuals who refer to treatment of gingival recession in the anterior site of the mandible that candidate to free gingival graft surgery and have these criteria will choose: -One of the mandibular central incisor has Miller class 1,2 or 3 gingival recession. - Systemically healthy -Don't use anticoagulatory drugs like Warfarin. - Didn't use antibiotic and corticosteroid at least during the past two months. -Aren't smoker or don't smoke more than 10 cigarette. -The females aren't pregnant or lactiferous . The sample size determined on the basis of preliminary sampling is 26 subjects. For the intervention group, 500 mg once daily Bromelain will be used on the day of surgery and continued for ten days and to the control group, placebo will give. 7 days after surgery, variables(pain, bleeding, and epithelialization of donor site) will survey on the basis of a questionnaire that will be completed by a third person who is unaware of the group of patients. Pain is directly based on VAS and the indirect method based on the number of analgesic tablets will be tested. Evaluation of epithelialization , will be repeated 10 days after surgery.

Registrant information

Name

Sara Soheilifar

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1824 7998

Email address

sara.soheilifar@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-04-09, 1394/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502089002N5**

Registration date: **2015-03-15, 1393/12/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Scientific title

Evaluating the efficacy of Bromelain on donor wound healing after free gingival surgery

Public title

Evaluating the efficacy of Bromelain on donor wound healing after free gingival surgery

Purpose

Supportive

Inclusion/Exclusion criteria

In this study , individuals who refer to treatment of gingival recession in the anterior site of the mandible

that candidate to free gingival graft surgery and have these criteria will choose: -One of the mandibular central incisor has Miller class 1,2 or 3 gingival recession. -Systemically healthy -Don't use anticoagulatory drugs like Warfarin. - Didn't use antibiotic and corticosteroid at least during the past two months. -Aren't smoker or don't smoke more than 10 cigarette. -The mesdames aren't pregnant or lactiferous .

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 26

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamedan University of Medical Sciences

Street address

Shahid Fahmide Street

City

Hamedan

Postal code

Approval date

2014-12-24, 1393/10/03

Ethics committee reference number

16/35/9/4782/پ

Health conditions studied

1

Description of health condition studied

Gingival recession

ICD-10 code

K06.0

ICD-10 code description

Gingival recession

(generalized)(localized)(postinfective)(post-operative)

Primary outcomes

1

Description

complete epithelialization of donor site

Timepoint

7 days after surgery and 10 days after surgery

Method of measurement

To evaluate of epithelialization, 3% hydrogen peroxide apply to the wound by a brush. If the epithelialization is completed, then hydrogen peroxide dose not diffuse into the connective tissue, and oxygen is not librated, ther for any bubble dose not observe. Otherwise , the epithelialization isn't completed.

2

Description

pain

Timepoint

7 days after surgery

Method of measurement

VAS

3

Description

the number of analgesic tablets that take by the patients

Timepoint

7 days after surgery

Method of measurement

the number that reported by the patients

Secondary outcomes

1

Description

bleeding

Timepoint

7 days after surgery

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group : Bromelain (capsule 500mg, oral , once a day for 10 days)

Category

Treatment - Drugs

2

Description

Control group : placebo (capsul , oral , once a day for 10 days)

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Department of Periodontology, School of Dentistry

Full name of responsible person

Sara Soheilifar

Street address

Shahid Fahmide Street

City

Hamedan

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Hamid Reza Abdosamadi

Street address

Shahid Fahmide Street

City

Hamedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

School of dentistry

Full name of responsible person

Fahime khoshkhoodie

Position

student

Other areas of specialty/work**Street address**

Shahid Fahmide Street

City

Hamedan

Postal code**Phone**

+98 81 3838 0572

Fax**Email**

fahime_khoshkhoodie68@yahoo.com

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

school of dentistry of Hamedan

Full name of responsible person

Sara Soheilifar

Position

Specialist in Periodontics

Other areas of specialty/work**Street address**

Shahid Fahmide Street

City

Hamedan

Postal code**Phone**

+98 81 3838 0572

Fax**Email**

sara.soheilifar@umsha.ac.ir

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

school of dentistry

Full name of responsible person

Fahime khoshkhoodie

Position

student

Other areas of specialty/work**Street address**

Shahid Fahmide Street

City

Hamedan

Postal code**Phone**

+98 81 3838 0572

Fax**Email**

fahime_khoshkhoodie68@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty*

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty