

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effectiveness of licorice gel on pain and wound healing in donor site of free gingival graft in hard palate

Protocol summary

Study aim

Evaluation of the effect of licorice gel on pain and wound healing in the hard palate

Design

A randomized, blinded, controlled clinical trial with a parallel group design, phase 3 on 12 patients.

Settings and conduct

This study is a randomized and double-blind controlled clinical trial (therapist and patients will not know which tube is placebo, and the pharmacist will deliver the tubes to the therapist in the same color and shape and numbered 1 and 2) and split mouth after Getting approval from the ethics committee will be done on 12 patients who are candidates for gum transplant in the periodontology department of Shiraz University of Medical Sciences, Faculty of Dentistry. In all selected patients, the test drug (gel containing licorice plant extract) will be placed on one side and the placebo drug will be placed on the other side by a sterile clean ear. The choice of test or control surgery will be done completely randomly. All surgeries will be performed by one surgeon and at an interval of one month for each patient. On the test side, the patients will be given a gel containing licorice plant extract (10%) twice a day for 7 days in the wound area. apply and the patients are advised not to eat anything for an hour after using the gel. After about a month, the other side will be operated and the patients are advised to use the placebo gel.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients in need of bilateral free gingival graft Age between 18_60 years Exclusion criteria: Diabetic patients Patients with uncontrolled blood pressure Patients with coagulation problem Patients that suffer from malignancy Patients who are under radiation Immunosuppressive patients

Intervention groups

Interventions include applying licorice gel and placebo on the palatal wound

Main outcome variables

Evaluation the amount of pain and wound healing in the donor site in the hard palate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221126056617N1**

Registration date: **2022-12-31, 1401/10/10**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-31, 1401/10/10**

Update count: **0**

Registration date

2022-12-31, 1401/10/10

Registrant information

Name

Raziye Ghodsi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4452 5041

Email address

rzghodsi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of licorice gel on pain and wound healing in donor site of free gingival graft in hard palate

Public title

Effect of licorice gel on wound healing in hard palate

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients in need of bilateral free gingival graft Age between 18_60 years

Exclusion criteria:

Diabetic patients Patients with uncontrolled blood pressure Patients with coagulation problem Patients that suffer from malignancy Patients who are under radiation Immunosuppressive patients

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

Randomized

Randomization description

12 people are individually assigned to two treatments by means of two blocks of 6 using the sealed envelope site, and after passing the wash out period, they receive the opposite treatment of the first treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher dose not know whether the gel is a placebo or test, and the pharmacist gives the gel to the researcher in similar tubes to the researcher. The patient is aware of the general nature of the study and knows that the licorice gel and placebo gel will be applied to him/her, but he/she did not know which side of licorice gel and which side of placebo gel will be applied.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Dental school, Ghasredasht Street, Shiraz Iran

City

Shiraz

Province

Fars

Postal code

71956-15878

Approval date

2022-11-14, 1401/08/23

Ethics committee reference number

IR.SUMS.DENTAL.REC.1401.084

Health conditions studied**1****Description of health condition studied**

Evaluation healing of donor site

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The degree of wound healing

Timepoint

Evaluation the degree of healing on days 7,14,and 21 after surgery

Method of measurement

Photography and H2O2 test

2**Description**

Degree of pain

Timepoint

Evaluation the amount of pain on days1,3,5,7, and14 after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Type of consumable:licoriece

gel10%,1ml per use,use the gel twice a day for 7 days,using a sterile Q-Tip 1ml of gel is applied.The gels are prepared manually by the pharmacist.

Category

Treatment - Drugs

2**Description**

Control group: Placebo gel,1ml twice a day for 7 days.The gels are prepared manually by the pharmacist

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faculty of Dentistry, Shiraz University of Medical Sciences

Full name of responsible person

Zahra Emami

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

Shiraz University of Medical Sciences

Full name of responsible person

Deputy of research and technology

Street address

7th floor ,Research and technology department,Shiraz University of Medical Sciences,Zand St.,Shiraz

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vcrdep@sums.ac.ir

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

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Raziye Ghodsi

Position

Periodontics 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**

Shiraz University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Medical doctor

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Person responsible for updating data

Contact

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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

Yes - There is 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

Title and more details about the data/document

Information about the main outcome can be shared

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

No special conditions are required to access the data

From where data/document is obtainable

E_mail:Rzghodsi1992@gmail.com Dental school, ghasredasht street,shiraz phone number: +989366779660 Raziye Ghodsi

What processes are involved for a request to access data/document

The applicant first sends an email to the above address and requests to receive these documents, after about 1 month these documents will be sent.

Comments