

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 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

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

#### 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

#### 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

**Street address**

Dental School, Ghasredasht Ave, Shiraz

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+98 71 3626 3193

**Email**

Zahra\_emami63@yahoo.com

**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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**Province**

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7134814336

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+98 71 3212 2430

**Email**

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**

Raziye GHodsi

**Position**

Periodontics Resident

**Latest degree**

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## Person responsible for updating data

### 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**  
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rzghodsi1992@gmail.com

## 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