

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of effect of propolis on palatal wound healing and pain management following harvesting free gingival graft

Protocol summary

Summary

The aim of this study is to evaluate the effect of propolis on palatal wound healing and pain management following harvesting free gingival graft. For this double-blind randomized clinical trial, 10 patients who required bilateral free gingival graft are selected. Following the surgery in control area, propolis-free oral ointment containing pectin, paraffin and carboxy methyl cellulose is applied over the palatal wound and the wound in the test area is protected by oral ointment containing 3.6 % propolis. The patient and the operator aren't informed about the type of the ointment. Level of pain and burning sensation are recorded on 1st, 3rd, 7th, 14th and 21st days following the surgery. Number of pain killers consumed and number of days patients take the pain killers are asked on 21st day. Bleeding in palatal area is evaluated on 7th, 14th, and 21st days. Dimensional changes and color match values are evaluated via photographs which are taken at baseline and 7th, 14th, 21st, 30th, 42nd days from palatal wound area. Dimensional changes are evaluated with AutoCAD software and predetermined scale. Color coordination of donor site and adjacent normal tissues are evaluated using Photoshop software. The thickness of the donor site is measured using a sterile kfile #15 on 4 sites of wound area at baseline and 30th, 42nd days and the mean value is recorded. The data between test and control groups will be compared by statistical analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015073123425N1**

Registration date: **2015-09-01, 1394/06/10**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-09-01, 1394/06/10

Registrant information

Name

Zahra Alizadeh Tabari

Name of organization / entity

Qazvin University of Medical Sciences, Qazvin Dental School

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences

Expected recruitment start date

2015-10-20, 1394/07/28

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of propolis on palatal wound healing and pain management following harvesting free gingival graft

Public title

Effect of propolis on palatal wound healing and pain management

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: no systemic disease interfere with the wound healing, no cigarette smoking, no allergy to honey
 Exclusion criteria: patients without cooperation during the study

Age
 No age limit

Gender
 Both

Phase
 N/A

Groups that have been masked
 No information

Sample size
 Target sample size: 20

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Qazvin University of Medical Sciences

Street address
 Qazvin Dental School, Qazvin University of Medical Sciences, Bahonar Blvd., Qazvin, Iran

City
 Qazvin

Postal code

Approval date
 2015-07-12, 1394/04/21

Ethics committee reference number
 IR.QUMS.REC.1394.80, IR.QUMS.REC.1394.79

Health conditions studied

1

Description of health condition studied
 gingival graft due to lack of attached gingiva

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
 pain level

Timepoint
 on 1st, 3rd, 7th, 14th and 21st days following the surgery

Method of measurement
 visual analogue scale

2

Description
 dimensional changes

Timepoint
 7th, 14th, 21st , 30th, 42nd days

Method of measurement
 Dimensional changes are evaluated via photographs which are taken at baseline and 7th, 14th, 21st , 30th, 42nd days from palatal wound area. Dimensional changes are evaluated with AutoCAD software and predetermined scale.

3

Description
 thickness of palatal donor site

Timepoint
 0, 30th and 42nd days

Method of measurement
 measured using a sterile kfile #15 on 4 sites of wound area at baseline and 30th, 42nd days and the mean value is recorded.

4

Description
 color match

Timepoint
 7th, 14th, 21st , 30th, 42nd days

Method of measurement
 Color coordination of donor site and adjacent normal tissues are evaluated using Photoshop software.

Secondary outcomes

1

Description
 burning sensation

Timepoint
 on 1st, 3rd, 7th, 14th and 21st days

Method of measurement
 by asking patients, yes or no

2

Description
 Number of pain killers consumed

Timepoint
 21st day

Method of measurement

by asking patients

3

Description

number of days patients take the pain killers

Timepoint

on 21st day

Method of measurement

by asking patient

4

Description

bleeding of the wound

Timepoint

on 7th, 14th, and 21st days.

Method of measurement

by rubbing the gauze on the wound/ yes or no

Intervention groups

1

Description

in control area, propolis-free oral ointment containing pectin, paraffin and carboxy methyl cellulose is applied over the palatal wound

Category

Treatment - Drugs

2

Description

in the test area is protected by oral ointment containing 3.6 % propolis.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin University of Medical Sciences

Full name of responsible person

Zahra Alizadeh Tabari

Street address

Qazvin Dental School, Qazvin University of Medical Sciences, Bahonar Blvd., Qazvin, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Zahra Alizadeh Tabari

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Farzaneh Dashkhaneh

Position

dental student

Other areas of specialty/work

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Person responsible for updating data

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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