

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the effect of mucous adhesive nifedipine on wound healing in the palate (clinical trials)

Protocol summary

Study aim

Evaluation the effect of mucous adhesive nifedipine on wound healing in the palate (clinical trials)

Design

Clinical trials with a control group, with parallel groups, triple-blind

Settings and conduct

The study will be conducted on patients referring to the oral medicine department of Babol Dental School, which has a gingival recession and need to take grafts in the palate area. For each treatment group, 20 samples and a total of 40 samples were considered. Patients, examiner and outcome measurer of this study are blind (triple-blind).

Participants/Inclusion and exclusion criteria

Selection criteria: patients undergoing gingival surgery requiring graft in the palate In the age range of 20 to 50 years; exclusion criteria: systemic conditions

Intervention groups

1. gingival graft surgery with mucous adhesive, 2. gingival graft surgery with mucous adhesive nifedipine

Main outcome variables

Clinical parameters include landry restoration index, manchester restoration index, and pain visual analogue scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190430043431N1**

Registration date: **2019-06-21, 1398/03/31**

Registration timing: **retrospective**

Last update: **2019-06-21, 1398/03/31**

Update count: **0**

Registration date

2019-06-21, 1398/03/31

Registrant information

Name

mina mollabnejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

mmotallebnejad@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-11, 1396/12/20

Expected recruitment end date

2019-06-19, 1398/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of mucous adhesive nifedipine on wound healing in the palate (clinical trials)

Public title

Evaluation the effect of mucous adhesive nifedipine on wound healing in the palate (clinical trials)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing gingival surgery requiring graft in the palate In the age range of 20 to 50 years

Exclusion criteria:

Systemic conditions

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The pharmacologist, who is the only person aware of the contents of each of the mucous of adhesives, provides 20 cards containing the nifedipine gel code, and 20 cards containing a non-nifedipine gel code. Then, each patient chooses to enter a control or case group by selecting each card.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients do not aware of the treatment group which they included. The outcome evaluator measures the study data without any knowledge about the type of treatment. The person who analyze data does not know the codes and he is blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Babol university of medical science

Street address
Ganjafrooz Ave.

City
Babol

Province
Mazandaran

Postal code
4717647745

Approval date
2018-02-26, 1396/12/07

Ethics committee reference number
MUBABOL.HRI.REC.1396.209

Health conditions studied

1

Description of health condition studied
Gingival recession

ICD-10 code
K06

ICD-10 code description
Gingival recession

Primary outcomes

1

Description
Landry restoration index

Timepoint
2, 4, 7, 14, and 30 days after surgery

Method of measurement
by Landry, Turnbull and Howley index

2

Description
Pain Visual Analogue scale

Timepoint
2, 4, 7, 14, and 30 day after surgery

Method of measurement
by Visual Analogue Scale

3

Description
Manchester restoration index

Timepoint
2, 4, 7, 14, and 30 days after surgery

Method of measurement
by Manchester index

Secondary outcomes

empty

Intervention groups

1

Description
Control group: gingival graft surgery with mucous adhesive

Category
Treatment - Surgery

2

Description
Intervention group: gingival graft surgery with mucous adhesive nifedipine

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral Medicine departmet of Babol dental faculty

Full name of responsible person

Mohaddeseh Emampanahi

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Ganjafrooz Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mina Motalebnejad

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Mina Motalebnejad

Position

full professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

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Position

full professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mohaddeseh Emampanahi

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