

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Comparison of Free gingival unit graft and free gingival graft for the Treatment of Gingival Recession

Protocol summary

Summary

Recession of marginal gingival causes different esthetic and functional problems. Free gingival graft can increase the width of attached gingival. There are significantly different vascular distributions in gingival regional districts, so conventional free palatal graft modified with the involvement of marginal gingival and papillary tissue (described as the gingival unit) may have an uncommon capacity for per fusion and survival on the exposed root surfaces. The aim of this study is to clinically evaluate the treatment of gingival recession by using gingival unit grafts compared with conventional palatal grafts. In this double-blind study 9 patients will be included based on inclusion criteria and surgical sites divided into two groups randomly in every patient. Case group (free gingival unit graft): the donor gingival unit graft was dissected from the palatal aspect of the maxillary premolars. Control group (conventional free gingival graft): the donor palatal graft was harvested from the palate corresponding to the premolar area but ± 2 mm away from the gingival margin. Landry index, pain index, esthetic index, root coverage percent will be checked 1, 3 and 6 months after surgery and the distance between CEJ and gingival sulcus will be checked 3 and 6 months after surgery. Statistical analyses will be performed using SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403061760N33**

Registration date: **2014-04-27, 1393/02/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-27, 1393/02/07

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research and Technology, Babol University of Medical Sciences

Expected recruitment start date

2014-03-11, 1392/12/20

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of Free gingival unit graft and free gingival graft for the Treatment of Gingival Recession

Public title

The Comparison of Free gingival unit graft and free gingival graft for the Treatment of Gingival Recession

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: there is a single two-way analysis of facial tissue depth of $2\text{mm} \leq X$ CEJ on anterior teeth or premolars; putting all subgroup analyzes of Miller class I / II; selected teeth without root fillings and no bleeding after probing; people over 18 years of age; ability to maintain good oral hygiene (% 20 O'Leary plaque score $\leq$); sufficient depth of vestibule. Exclusion criteria: pregnancy; interfere with the healing agents (corticosteroids, anti-cancer) or medicines that may lead to gingival enlargement; smoking; administration has banned any local or systemic disease, periodontal surgery; traumatic brushing techniques, brushing hard or abrasive toothpastes; history of periodontal surgery in the area in the past 2 years; the use of removable prosthodontic or orthodontic appliances in the area; known allergies to materials used in surgery.

Age

From **18 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **9**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Babol University of Medical sciences

Street address

Babol University of Medical sciences, Ganjafroz Avenue

City

Babol

Postal code

Approval date

2014-03-08, 1392/12/17

Ethics committee reference number

30/3810/پ

Health conditions studied

1

Description of health condition studied

Gingival Recession

ICD-10 code

K06.0

ICD-10 code description

Gingival Recession

Primary outcomes

1

Description

Treatment of Gingival Recession

Timepoint

Six months after surgery

Method of measurement

clinical

Secondary outcomes

1

Description

Healing

Timepoint

One, three and six months after surgery

Method of measurement

Indexed repair Landry

2

Description

Pain relief after surgery

Timepoint

One, three and six months after surgery

Method of measurement

pain Index (VAS)

3

Description

esthetic

Timepoint

One, three and six months after surgery

Method of measurement

Esthetic index (VAS)

4

Description

Percentage of root coverage (RC)

Timepoint

One, three and six months after surgery

Method of measurement

Clinical

Description

Clinical Attachment Level (CAL)

Timepoint

Three and six months after surgery

Method of measurement

Mm

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

Case group (free gingival unit graft): the donor gingival unit graft was dissected from the palatal aspect of the maxillary premolars. Care will be taken to obtain a graft thickness of 1 mm. The graft will be then contoured, adapted, sutured into position at the level or coronal to the CEJ and the donor site will be sutured with 4-0 VICRYL suture too. Both donor and recipient site will be covered with periodontal dressing. All of the patients will be devised to rinse once daily with 0.2% of Chlorhexidine for 3 weeks. Systemic antibiotic (Amoxicillin 500mg tid) will be administered for 1 week and sutures will be off after 10 days.

Category

Treatment - Surgery

2**Description**

Control group (conventional free gingival graft): the donor palatal graft was harvested from the palate corresponding to the premolar area but 2 mm away from the gingival margin. Care will be taken to obtain a graft thickness of 1 mm. The graft will be then contoured, adapted, sutured into position at the level or coronal to the CEJ and the donor site will be sutured with 4-0 VICRYL suture too. Both donor and recipient site will be covered with periodontal dressing. All of the patients will be devised to rinse once daily with 0.2% of Chlorhexidine for 3 weeks. Systemic antibiotic (Amoxicillin 500mg tid) will be administered for 1 week and sutures will be off after 10 days.

Category

Treatment - Surgery

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

Dental colleges of Babol, Babol University of Medical Sciences,

Full name of responsible person

Dr. Mohadese Yazdan Panah

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

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

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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

Vice Chancellor for Research and Technology, Babol 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**

Dental School, Babol University of Medical Sciences

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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