

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Clinical Trial of Comparison of Collagen Membrane and Space Maker With Subepithelial Connective Tissue Graft (Modified Method) in Treatment of Gingival Recession

Protocol summary

Summary

Aim: The aim of this clinical trial is to compare the changes in clinical periodontal variables between two methods of guided tissue regeneration and connective tissue graft in the treatment of gingival recession. Study design: Randomized, single blind, no placebo, two-centered. Population: Patients aged 20-60 years, both male and female. Inclusion criteria: Class one or two Miller's gingival recessions with at least 3 mm depth in incisors and premolars; esthetic problem or root sensitivity (sensitivity is characterized by blowing air by means of air syringe on root surface for 3 seconds from 2 cm distance to the tooth and asking the patient regard root sensitivity); patient capability for plaque control. Exclusion criteria: Systemic disease; pregnancy; breastfeeding. Sample size: Twenty four samples in two groups; each containing 12 samples. Interventions: Utilization of collagen membrane with space maker and subepithelial connective tissue graft (modified method) in treatment of gingival recession. Investigation duration: six months. Primary Result: Pocket depth, clinical attachment level, depth and width of recession, width of keratinized tissue.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051912487N5**
Registration date: **2014-06-14, 1393/03/24**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-14, 1393/03/24

Registrant information

Name

Shirin Amini

Name of organization / entity

Khorasgan Branch, Islamic Azad University, Isfahan

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-09-23, 1390/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial of Comparison of Collagen Membrane and Space Maker With Subepithelial Connective Tissue Graft (Modified Method) in Treatment of Gingival Recession

Public title

Comparison of two Gingival Recession Treatment Techniques

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Class one or two Miller's gingival

recession with at least 3 mm depth in incisors and premolars; esthetic problem or root sensitivity (sensitivity is characterized by blowing air by means of air syringe on root surface for 3 seconds from 2 cm distance to the tooth and asking the patient regard root sensitivity); patient capability for plaque control. Exclusion criteria: Systemic disease; smoking; gingival inflammation; allergy to collagen products

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization: The receded tooth in each site of a patient's mouth were randomly selected via throwing the coin to treat by one of the treatment methods. Blindness: All the variables were measured by another examiner who was blind to the selected treatment modalities for each tooth.

Secondary Ids

empty

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

Ethics Committee of Khorasgan Branch, Islamic Azad University

Street address

Khorasgan Branch, Islamic Azad University, University Boulevard, Arghavaniyeh street, Eastern Jey Street, Isfahan, Iran

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81595158

Approval date

2010-05-24, 1389/03/03

Ethics committee reference number

07301/D/890303

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

Gingival recession

ICD-10 code

K06.9

ICD-10 code description

Gingival recession (post-operative)

Primary outcomes**1****Description**

Probing depth

Timepoint

Before and one, 2, 3, 6 months after treatment

Method of measurement

Measuring of the pocket depth in mm by a Williams periodontal probe (Hu-Friedy, Chicago, IL, US)

2**Description**

Clinical attachment level

Timepoint

Before and one, 2, 3, 6 months after treatment

Method of measurement

Measuring of the clinical attachment level in mm by a Williams periodontal probe (Hu-Friedy, Chicago, IL, US)

3**Description**

Depth of gingival recession

Timepoint

Before and one, 2, 3, 6 months after treatment

Method of measurement

Measuring of the gingival recession depth in mm by a Williams periodontal probe (Hu-Friedy, Chicago, IL, US)

4**Description**

Width of gingival recession

Timepoint

Before and one, 2, 3, 6 months after treatment

Method of measurement

Measuring of the gingival recession width in mm by a Williams periodontal probe (Hu-Friedy, Chicago, IL, US)

5**Description**

Width of keratinised tissue

Timepoint

Before and one, 2, 3, 6 months after treatment

Method of measurement

Measuring of the keratinized tissue width in mm by a Williams periodontal probe (Hu-Friedy, Chicago, IL, US)

Secondary outcomes

empty

Intervention groups

1

Description

Connective tissue graft

Category

Treatment - Surgery

2

Description

Using of the collagen membrane (Biogide manufactured by Geistlich company, Wolhusen, Swiss) and space maker (Gingostat manufactured by GABA VEBAS srl, Rome, Italy)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Private practice and Department of Periodontology, Dental School, Khorasgan Branch, Islamic Azad Univ

Full name of responsible person

Dr Shirin Amini

Street address

Dental School, Khorasgan Branch, Islamic Azad University, University Boulevard, Arghavanieh Street, Eastern Jey Street, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice- Chancellor of Islamic Azad University Khorasgan Branch

Full name of responsible person

Esfahanian, Vahid

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Dental School, Khorasgan Branch, Islamic Azad University, University Boulevard, Arghavanieh Street, Eastern Jey Street, Isfahan, Iran

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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

Research Vice- Chancellor of Islamic Azad University Khorasgan Branch

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

Department of Periodontology, Dental School, Khorasgan Branch, Islamic Azad University

Full name of responsible person

Dr Faraz Teimuri

Position

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empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty