

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of palatal connective tissue graft usage with and without periosteum as a membrane along with Bio-Oss in treatment of vertical alveolar bone defects

Protocol summary

Summary

Aims: Usage of palatal connective tissue graft with and without periosteum along with Bio-Oss in treatment of vertical alveolar bone defects. Study design: Randomized; Interventional; Double blind; No Placebo usage; Uni-center; Crossover. a- Study population: With age limit; no sex limit. Inclusion Criteria: Plaque Index 25% or less before surgery; teeth with mobility of Miller grade III or less; Vital teeth or nonvital teeth with proper endodontic treatment; patients with moderate to severe chronic periodontitis; radiologic approval of a pair of interdental vertical bone defects in two non-adjacent teeth; Clinical attachment loss more than 5 millimeters; defect depth must be at least 3 millimeters; intrabony two or three walls defects. Exclusion Criteria: Patients with any systemic disorders; pregnant and breast feeder patients; Systemic antibiotic usage in the last three months; abnormal platelet count in the last month before surgery; Grade III of Furcation involvement; History of periodontal surgery in the last six months. Sample size: 15 patients; 30 sites. b- Intervention/Control: Intervention: Palatal connective Tissue graft with periosteum as a membrane With Bio-oss. Control: Palatal connective Tissue graft without periosteum as a membrane With Bio-oss. Time of intervention: 6 months. Primary or under study outcome measures: Probing Pocket Depth; Clinical Attachment Level; Defect fill; Gingival margin status; Crestal bone status; amount of defect resolve.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012101611133N1**

Registration date: **2013-01-31, 1391/11/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-31, 1391/11/12

Registrant information

Name

Mohamadreza Ghafari

Name of organization / entity

Islamic Azad Dental School Khorasgan Branch,
(Isfahan), Iran

Country

Iran (Islamic Republic of)

Phone

+98 31 1535 4053

Email address

mr.ghafari@khuisf.ac.ir

Recruitment status

Recruitment complete

Funding source

Private

Expected recruitment start date

2012-04-03, 1391/01/15

Expected recruitment end date

2012-10-06, 1391/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of palatal connective tissue graft usage with and without periosteum as a membrane along with Bio-Oss in treatment of vertical alveolar bone defects

Public title

Usage of palatal connective tissue graft in treatment of vertical alveolar bone defects

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Plaque Index 25% or less before surgery; teeth with mobility of Miller grade III or less; Vital teeth or nonvital teeth with proper endodontic treatment; patients with moderate to severe chronic periodontitis; radiologic approval of a pair of interdental vertical bone defects in two non-adjacent teeth; Clinical attachment loss more than 5 millimeters; defect depth must be at least 3 millimeters; intrabony two or three walls defects. Exclusion Criteria: Patients with any systemic disorders; pregnant and breast feeder patients; Systemic antibiotic usage in the last three months; abnormal platelet count in the last month before surgery; Grade III of Furcation involvement; History of periodontal surgery in the last six months.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad Dental School Khorasgan Branch, (Isfahan), Iran

Street address

Islamic Azad University Khorasgan (Isfahan) Branch, University Boulevard, Arghavanieh, Eastern Jay Street, Isfahan, Iran. Isfahan Isfahan Iran, Islamic Republic Of

City

Isfahan

Postal code

Approval date

2012-05-26, 1391/03/06

Ethics committee reference number

91030609501

Health conditions studied

1

Description of health condition studied

Chronic Periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes

1

Description

Probing Pocket depth

Timepoint

0 and 6 months

Method of measurement

per millimeters by means of a UNC-15 Periodontal Probe

2

Description

Clinical Attachment Level

Timepoint

0 and 6 months

Method of measurement

per millimeters by means of a UNC-15 Periodontal Probe

3

Description

Gingival margin status

Timepoint

0 and 6 months

Method of measurement

per millimeters by means of a UNC-15 Periodontal Probe

4

Description

Defect Bone Fill

Timepoint

0 and 6 months

Method of measurement

per millimeters by means of a UNC-15 Periodontal Probe

5

Description

Crestal Bone Status

Timepoint

0 and 6 months

Method of measurement

per millimeters by means of a UNC-15 Periodontal Probe

6

Description

amount of defect resolve

Timepoint

0 and 6 months

Method of measurement

per millimeters by means of a UNC-15 Periodontal Probe

Secondary outcomes

empty

Intervention groups

1

Description

Palatal connective Tissue graft with periosteum as a membrane

Category

Treatment - Surgery

2

Description

Palatal connective Tissue graft without periosteum as a membrane

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad Dental School Khorasgan Branch, (Isfahan), Iran

Full name of responsible person

Mohamadreza Ghafari

Street address

Islamic Azad University Khorasgan (Isfahan) Branch, University Boulevard, Arghavanieh, Eastern Jay Street, Isfahan, Iran.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad Dental School Khorasgan Branch, (Isfahan), Iran

Full name of responsible person

Vahid Esfahanian

Street address

Islamic Azad University Khorasgan (Isfahan) Branch, University Boulevard, Arghavanieh, Eastern Jay Street, Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad Dental School Khorasgan Branch, (Isfahan), Iran

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

Islamic Azad Dental School Khorasgan Branch, (Isfahan), Iran

Full name of responsible person

Mohamadreza Ghafari

Position

Post-graduate Student of Periodontics

Other areas of specialty/work

Street address

Islamic Azad University Khorasgan (Isfahan) Branch, University Boulevard, Arghavanieh, Eastern Jay Street, Isfahan, Iran

City

Isfahan

Postal code

Phone

+98 31 1535 4001

Fax

Email

shahabgh1982@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad Dental School Khorasgan Branch, (Isfahan), Iran

Full name of responsible person

Mohamadreza Ghafari

Position

Post_graduated Student Of Periodontics

Other areas of specialty/work

Street address

Islamic Azad University Khorasgan (Isfahan) Branch, University Boulevard, Arghavanieh, Eastern Jay

Street, Isfahan, Iran

City

Isfahan

Postal code

Phone

+98 31 1535 4001

Fax

Email

shahabgh1982@gmail.com

Web page address

City

Isfahan

Postal code

Phone

+98 31 1535 4001

Fax

Email

shahabgh1982@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad Dental School Khorasgan Branch,
(Isfahan), Iran

Full name of responsible person

Mohamadreza Ghafari

Position

Post-Graduated Student Of Periodontics

Other areas of specialty/work

Street address

Islamic Azad University Khorasgan (Isfahan) Branch,
University Boulevard, Arghavanieh, Eastern Jay
Street, Isfahan, Iran

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