Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative evaluation of papilla reconstruction between adjacent implants using bone and connective tissue graft in patients referring to Periodontics Department of Hamadan School of Dentistry

Protocol summary

Summary

Aim: Comparison of bone and connective tissue graft procedures in papilla reconstruction between adjacent implants bone and connective tissue graft in patients referring to Periodontics Department of Hamedan School of Dentistry Design: Single blinded randomized clinical trial Setting: The eligible patients who are candidate to replacement of adjacent implants will be assigned to two different block randomized treatment groups of bone and connective tissue graft. Inclusion criteria: missing two adjacent teeth so that there is the possibility of placing two implants in bone site; at least 3 months has been passed since the area being edentulous Exclusion criteria: periodontal plastic surgery or Bone graft history in the area; presence of any systemic disease (Including uncontrolled diabetes, osteomyelitis) that may affect implant placement or soft tissue management; smoking; pregnancy. For all patients during surgery anesthetic injection, flap and drilling steps in implant site will be done. Intervention (a): FDBA bone block that has been immersed in saline will be used and for adaptation to area will be trimmed by scissor and fixed in place with titanium screw. Intervention (b): The palatal mucosa between canine and mesial line angle of first molar will be used as source of connective tissue. the graft will be placed on top of the alveolar bone between two implants and then sutured with an absorbable suture. Primary outcome: Papilla height based on papilla index(Jemt) Secondary outcome: Vertical distance between tip of papilla and alveolar crest based on radiographic evaluation using radiopaque indicator

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072414142N1**

Registration date: **2013-08-08, 1392/05/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-08, 1392/05/17

Registrant information

Name

Shilan Razaghi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-06-20, 1392/03/30

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of papilla reconstruction

between adjacent implants using bone and connective tissue graft in patients referring to Periodontics Department of Hamadan School of Dentistry

Public title
Comparison of soft tissue reconstruction between adjacent implants using bone and connective tissue graft in patients missing two adjacent teeth
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: missing two adjacent tooth so that there is the possibility of placing two implants in bone site; the area is edentulous for at least 3 months
Exclusion criteria: periodontal plastic surgery or Bone graft history in the area; presence of any systemic disease (Including uncontrolled diabetes, osteomyelitis) that may affect implant placement or soft tissue management; smoking; Pregnancy
Age
From **25 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee, Hamadan University of Medical Sciences
Street address
Postcode: 65178-38377, Periodontics Department, School of Dentistry, Shahid Fahmideh Street, Hamadan
City
Hamedan
Postal code
65178-38377
Approval date
2013-06-12, 1392/03/22
Ethics committee reference number
16/35/9/757/د/پ

Health conditions studied

1

Description of health condition studied
missing two adjacent teeth, with bone resorption and papilla loss in the area
ICD-10 code
k08.2
ICD-10 code description
Atrophy of edentulous alveolar ridge

Primary outcomes

1

Description
Papilla height based on papilla index
Timepoint
3 months after intervention,6 months after intervention
Method of measurement
Qualitative determination of vertical distance between the tip of papilla to the line connecting Zenith of soft tissue margin at adjacent crowns based on grading system of Papilla index (Jemt).This index is classified into five grades (0,1,2,3,4) .

Secondary outcomes

1

Description
Distance from the tip of the papilla to the alveolar crest
Timepoint
3 months after intervention,6 months after intervention
Method of measurement
Quantitative measurement of vertical distance from the tip of papilla between two implants to the alveolar crest in periapical radiography using radiopaque indicator in millimeters.

Intervention groups

1

Description
FDBA bone block that has been immersed in saline will be used and for adaptation to the area will be trimmed by scissor and fixed in place with titanium screw.
Category
Treatment - Surgery

2

Description
The palatal mucosa between the canine and the mesial line angle of first molar will be used as the source of

connective tissue. Connective tissue graft harvested from the palate by making a single incision parallel and at a distance of 2mm from the gingival margin using a scalpel with a size 15 blade. After horizontal and vertical incisions the graft will be separate and donor site sutured.The graft will be placed on top of the alveolar bone between two implants and then sutured with an absorbable suture.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan University of Medical Sciences

Full name of responsible person

Dr Syed Reza Arabi

Street address

Postcode: 65178-38377, Periodontics Department, School of Dentistry, Shahid Fahmideh Street, Hamadan

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research and technology, Hamadan University of Medical Sciences

Full name of responsible person

Dr. Heidar Tavilani

Street address

Postcode: 65178-518, School of Medicine, Shahid Fahmideh Street, Hamadan

City

Hamedan

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, Hamadan 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

Hamadan University of Medical Sciences

Full name of responsible person

Dr Syed Reza Arabi

Position

Assistant

Other areas of specialty/work

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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