

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 1084

Email address

sh.razaghi@umsha.ac.ir

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

Street address

Postcode: 6517838377, Periodontics Department,
School of Dentistry, Shahid Fahmideh Street,
Hamadan

City

Hamedan

Postal code

6517838377

Phone

+98 81 1838 1086

Fax

+98 811838105

Email

sr_arabi@yahoo.com

Web page address

Person responsible for scientific 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

Street address

Postcode: 6517838377, Periodontics Department,
School of Dentistry, Shahid Fahmideh Street,
Hamadan

City

Hamedan

Postal code

6517838377

Phone

+98 81 1838 1086

Fax

+98 81 1838 1085

Email

sr_arabi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Dr Shilan Razaghi

Position

Periodontics resident

Other areas of specialty/work**Street address**

Postcode: 6517838377, Periodontics Department,
School of Dentistry, Shahid Fahmideh Street,
Hamadan

City

Hamedan

Postal code

6517838377

Phone

+98 81 1838 1086

Fax

+98 81 1838 1085

Email

sh.razaghi@umsha.ac.ir; shilan.r@gmail.com;
sh_razaghi@yahoo.com

Web page address**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