Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison between acellular dermal matrix and connective tissue graft on vertical soft tissue thickness during submerged implant insertion

Protocol summary

Study aim

determination of alloderm and Connective Tissue Graft (CTG) on vertical soft tissue thickness on two-stage implant insertion

Design

Randomized two-arm parallel, double-blind trial, sample size 20 (10 patients in each group)

Settings and conduct

In this study, 1 hour before surgery, the patient receives 1 gram of prophylactic dose of amoxicillin, the procedure is then continued at 500 mg 3 times a day for 1 week after the intervention .The entire surgical procedure is performed by a surgeon. Buccal flap elevates with full thickness flap and vertical soft tissue dimension measured. Perio probe insert on alveolar ridge on implant insertion site. If vertical dimension of soft tissue was more than 3mm the patient went out of the study. After implant insertion in first group connective tissue graft (CTG) placed and in the second group ADM was placed in 10*10 mm dimension on alveolar ridge due to randomization. Flap sutured with 0/4 silk suture. And after 3 month recalling the patient happened and on healing abutment placement measurement of soft tissue thickness evaluated and reported by the blinded examiner who was not aware of belonging of patient to each groups.

Participants/Inclusion and exclusion criteria

1-patients candidate for implant treatment 2-thin crestal mucosal tissue (2 mm or less); partial edentulousness in different areas of the mouth 3-no bone augmentation process before and during implant placement.

Intervention groups

CTG and alloderm insertion on a two-stage implant for evaluation of these materials on progresstion and improvement of soft tissue around dental implants

Main outcome variables

soft tissue thickness around implant

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211003052658N1**
Registration date: **2021-11-07, 1400/08/16**
Registration timing: **retrospective**

Last update: **2021-11-07, 1400/08/16**
Update count: **0**

Registration date

2021-11-07, 1400/08/16

Registrant information

Name

amin mohammadpourkolde

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4212 5497

Email address

aminmpkld71@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-23, 1400/03/02

Expected recruitment end date

2021-08-29, 1400/06/07

Actual recruitment start date

2021-07-24, 1400/05/02

Actual recruitment end date

2021-10-19, 1400/07/27

Trial completion date

2021-10-23, 1400/08/01

Scientific title

Comparison between acellular dermal matrix and connective tissue graft on vertical soft tissue thickness during submerged implant insertion

Public title
Comparison between acellular dermal matrix and connective tissue graft on vertical soft tissue thickness during submerged implant insertion

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Thin crestal mucosal tissue (2 mm or less) Partial edentulousness in different areas of the mouth No bone agmentation process before and during implant placement

Exclusion criteria:
Patients undergoing soft and hard tissue regeneration treatments Implant loss in the area Patients under 18 years of age Has a medical contraindication for implants Has a history of periodontitis, has a history of uncontrolled diabetes and smoking and alcohol consumption Systemic disease that interferes with implant placement, history of radiation therapy and chemotherapy

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **20**
Actual sample size reached: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals who have been included in the study based on inclusion and exclusion criteria, randomly allocate into control and test group through randomized block method. Each block will contain 2,4 or 8 patient. After completion of each block treatment will be done by a randomized permutation on patient. Blocks and permutations on each block will create by agricolae package in R software with a definite seed. The number of the seed provide the possibility of recreation of random sequence. regard to this package number of block, size of block, sequence in each block and type of each patient treatment will present as outcome of the software.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients included in the study did not know that they belonged to the control and intervention groups. And measurements are made by another person during the first and second stages who does not know that the treated people belong to the control and intervention groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences

Street address
Qavin Shahid bahonar bolvar .Qazvin univercity of medical science

City
Qazvin

Province
Qazvin

Postal code
3419915315

Approval date
2021-07-20, 1400/04/29

Ethics committee reference number
ir.qums.rec.1400.187

Health conditions studied

1

Description of health condition studied
mucosal thinness in relation to peri-imlant disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
soft tissue thickness

Timepoint
on implant insertion and on healing abutment placement

Method of measurement
with periodontal probe and gage guide

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: CTG placement

Category

Treatment - Other

2

Description

Intervention group 2: ADM placement

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin university of medical science

Full name of responsible person

Amin Mohammadpour Kolde

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Mehdi Mirhashemi

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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

Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Amin Mohammadpour Kolde

Position

Resident

Latest degree

Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable