

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Clinical and histological comparison of collagen membrane and acellular dermal matrix in peri_implant vertical soft tissue thickening

Protocol summary

Study aim

Determining the clinical and histological effect of collagen membrane and acellular dermal matrix in increasing the vertical thickness of soft tissue on implants in patients referred to the implant department of Islamic Azad University of Tehran

Design

A single-blind clinical trial is performed and 24 eligible patients are performed in one center

Settings and conduct

The study will be performed clinically and histologically in Tehran Azad Dental School and the clinician and pathologist will be unaware of the grouping and the grouping will be done by the researcher

Participants/Inclusion and exclusion criteria

Inclusion criteria: tissue thickness in vertical dimension (2 mm or less), healthy soft tissue, partial edentulous of posterior of jaws, presence of at least 4 mm keratinized tissue
Exclusion criteria: bone agmentation process , O 'LEARY plaque control index more than 20%, smoking, presence of systemic disease, use of drugs ,pregnancy

Intervention groups

Collagen membrane group Acellular Dermal Matrix (ADM) group

Main outcome variables

Soft tissue thickness, Amount of collagen, Inflammation rate, Vascular density

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210510051251N1**

Registration date: **2021-11-21, 1400/08/30**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-21, 1400/08/30**

Update count: **0**

Registration date

2021-11-21, 1400/08/30

Registrant information

Name

meysam sanginan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8828 5796

Email address

sanginan.m@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-12, 1400/07/20

Expected recruitment end date

2022-02-09, 1400/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical and histological comparison of collagen membrane and acellular dermal matrix in peri_implant vertical soft tissue thickening

Public title

Comparison of collagen and dermal matrix in soft tissue thickening

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Thin vertical soft tissue thickness (less than 2 mm) 4 mm keratinized tissue at least Partial edentulous in posterior of jaws Healthy soft tissue

Exclusion criteria:

Need to bone augmentation procedure O' LEARY plaque index more than 20% Tobacco consumption Systemic disease related to soft & hard tissue healing Drug consumption related to soft & hard tissue healing Pregnancy

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done in 6-blocks pattern in such a way that three blocks belong to the collagen membrane group (CM) and three blocks belong to the acellular dermal matrix group (ADM). Each sample is assigned to a group by tossing a coin. Find that the valve belongs to the CM group and the line belongs to the ADM group. This process is performed 4 times until finally 24 patients are included in the study

Blinding (investigator's opinion)

Single blinded

Blinding description

Evaluators of results and data analysts are uninformed from the study groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the School of Dentistry, Tehran Azad University of Medical Sciences

Street address

9th Neystan Ave., Pasdaran Town

City

Tehran

Province

Tehran

Postal code

19585175

Approval date

2020-05-09, 1399/02/20

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.019

Health conditions studied

1

Description of health condition studied

Thin peri-implant soft tissue thickness

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Soft tissue thickness

Timepoint

Base line, 2 months

Method of measurement

The thickness of the soft tissue in the center of the implant will be measured with a UNC periodontal probe (Hu-Friedy, USA) relying on the lingual flap

2

Description

Amount of collagen

Timepoint

Base line, 2 months

Method of measurement

The biopsy specimens will be placed in paraffin blocks after fixation and microscopic incisions 3-4 mm thick will be prepared. The prepared sections will then be stained with Masson trichrom to evaluate the amount of collagen

3

Description

Inflammation rate

Timepoint

Base line, 2 months

Method of measurement

Biopsy specimens are stained with hematoxylin-eosin to measure the severity of inflammation and will be classified to mild, moderate, and severe

4

Description

Vascular density

Timepoint

Base line, 2 months

Method of measurement

Immunohistochemical staining with CD34 monoclonal antibody prepared from mice will be used to evaluate blood vessels

Secondary outcomes

empty

Intervention groups

1

Description

Collagen membrane group: The membranes are 15 x 20 mm in size and are shaped according to the implant site to prevent the adjacent teeth from invading and to adapt to the newly placed implant. The membrane expands 5 mm at the buccal surface and 5 mm at the lingual surface to better fit the area and complete implant coverage. Once the membrane is in place, the flaps will be brought closer together and sutured with 0-5 nylon thread (Supa, Iran) using the Single Interrupted technique.

Category

Treatment - Surgery

2

Description

Acellular group of dermal matrix: The matrixs are 15 x 20 mm in size and are shaped according to the implant site to prevent the adjacent teeth from invading and to adapt to the newly placed implant. The membrane expands 5 mm at the buccal surface and 5 mm at the lingual surface to better fit the area and complete implant coverage. Once the membrane is in place, the flaps will be brought closer together and sutured with 0-5 nylon thread (Supa, Iran) using the Single Interrupted technique.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School of Islamic Azad University of Tehran

Full name of responsible person

Meysam Sanginan

Street address

9th Neystan AVE., Pasdaran Town

City

Tehran

Province

Tehran

Postal code

19585175

Phone

+98 21 8828 5796

Email

sanginan.m@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Islamic Azad University of Tehran

Street address

9th Neystan AVE., Pasdaran Town

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 8828 5796

Email

sanginan.m@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Islamic Azad University of Tehran

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Dr Nima Nadafpour

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

9th Neystan AVE., pasdaran Town

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2245 4571

Email

nima.na04@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Meysam Sanginan

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

9th Neystan AVE., Pasdaran Town

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 8828 5796

Email

sanginan.m@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Nima Nadafpour

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

9th Neystan AVE., Pasdaran Town

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

nima.na04@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

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

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

Analytic Code

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

Data Dictionary

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