

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparison of Gingival Dimensional Changes Around the Teeth Using Allogenic and Xenogenic matrix in Thin Gingiva Patients

Protocol summary

Study aim

The aim of this study is comparison of Gingival dimensional changes around the teeth using Matrix Allogenic and Xenogenic Matrix.

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

Patients referred to department of periodontics, Shahid Beheshti University of Medical Sciences; first, all patients undergo phase 1 periodontal treatment. Then, in the next stage, the surgery is done using the CAF (Coronally Advanced Flape) technique in the receptor area. The graft are placed between the teeth and the flap, then taken to the suture area. At intervals 2 to 4 weeks and then monthly one day after surgery for prophylaxis patients. At intervals of two weeks, three months, six months and one year after surgery, Clinical parameters are measured by the periodontal department Resident who was not aware of the process of research and treatment for each of the teeth.

Participants/Inclusion and exclusion criteria

Not having proper gingival thickness (less than 1 mm); good health (plaque rate based on O'Leary index below 20%); pocket depth is less than 3 mm; no smoking; no orthodontic treatments; no pregnancy; no occlusal trauma; no periodontal surgeries in the last 12 months; no severe malocclusion in the examined area; no oral mucosal diseases and no systemic diseases.

Intervention groups

Patients are divided into two groups: Allograft and Xenograft surgery.

Main outcome variables

Gingival thickness; gingival recession; keratinized gingiva width; pocket depth; clinical attachment loss; plaque Index and gingival Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190617043911N1**

Registration date: **2019-07-02, 1398/04/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-02, 1398/04/11**

Update count: **0**

Registration date

2019-07-02, 1398/04/11

Registrant information

Name

Hoda Parandeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4462 3128

Email address

parandeh94@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Gingival Dimensional Changes Around the Teeth Using Allogenic and Xenogenic matrix in Thin Gingiva Patients

Public title

Effect Allogenic and Xenogenic matrix in treatment of thin gingiva

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Not having Proper Gingival Thickness (less than 1 mm)
Good health (Level of plaque based on the O'Leary index below 20%) Pocket Depth less than 3 mm

Exclusion criteria:

Smoking Orthodontic Treatments Pregnancy Occlusal Trauma Periodontal Surgeries in the last 12 months Severe Malocclusion in the examined area Oral Mucosal diseases Systemic disease

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **3**

Tooth

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization, Individual, Sealed Envelope

Blinding (investigator's opinion)

Single blinded

Blinding description

Resident of Periodontics who is not aware of the Process of Research and Treatment for each of the Teeth and Statistics specialist

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences (dental College)

Street address

Shahid Beheshti University of Medical Sciences (dental College), Daneshjoo Ave, Velenjak, Shahid Chamran Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2016-09-27, 1395/07/06

Ethics committee reference number

IR.SBMU.RIDS.REC.B95.269

Health conditions studied

1

Description of health condition studied

Gingival recession

ICD-10 code

K06.0

ICD-10 code description

Gingival recession (generalized)(localized)(postinfective)(post-operative)

Primary outcomes

1

Description

Variable: Gingival Thickness, lacking proper Gingival Thickness (less than 1 mm)

Timepoint

At the Base of the study (before the intervention) and 3 weeks, 2 months, 6 months and one year after the surgery, increased Gingival Thickness with two Materils of mucoderm and Alloderm.

Method of measurement

Gingival thickness measurements using the Sperider whit Rubberpoint and digital caliper

Secondary outcomes

1

Description

En Variable: Gingival Recession, Patients who have Gingival Recession

Timepoint

At the Base of the study (before the intervention) and 3 weeks, 2 months, 6 months and one year after the surgery, increased Gingiva with two Materils of mucoderm and Alloderm

Method of measurement

Gingival Recession measurements using the digital caliper

Intervention groups

1

Description

Intervention group: Mucoderm (Xenograft)

Category

Treatment - Surgery

2

Description

Control group: Alloderm (Allograft)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Dental School

Full name of responsible person

Hoda Parandeh

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info@sbmu.ac.ir

Web page address

http://www.sbu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Azita Tehranchi

Street address

Shahid Beheshti Dental School, Daneshjoo Ave.,
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+98 21 2240 3194

Email

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Web page address

http://www.sbu.ac.i

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hoda Parandeh

Position

Post graduate

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All participants with undetectable personal data of
people sharing

When the data will become available and for how long

Starting the access period from 1398

To whom data/document is available

All people can use data.

Under which criteria data/document could be used

Certain conditions are not required.

From where data/document is obtainable

Hoda Parandeh, Shaheed Beheshti Dental School, phone
number: +98 21 2217 5350, parandeh94@gmail.com

What processes are involved for a request to access data/document

The applicant can access the data after 48 hours after
requesting an email

Comments