

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Periodontal phenotype modification in orthodontic patients

Protocol summary

Study aim

This study aimed to assess the efficacy of phenotype modification around teeth following the use of an allogenic grafting material and a xenogeneic collagen matrix.

Design

A non-randomized, non-blinded, single group clinical trial on 15 patients

Settings and conduct

This study would be conducted at the Department of Periodontics, Shahid Beheshti University of Medical Sciences. In cases that surgery would be performed during orthodontic treatment, active treatment would be interrupted 3 weeks prior to the surgery and postponed for 4 months following surgical intervention. An intracrevicular incision would be used to raise a full-thickness flap. Periosteal incisions would be made for passive flap advancement. Demineralized freeze-dried bone allograft would be placed on the bone surface and covered with a xenogeneic collagen matrix. The collagen matrix would be secured with sling sutures. Flap closure would be achieved with internal vertical mattress sutures at interdental areas.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ≥ 18 years of age; thin periodontal phenotype; absence of gingival inflammation; probing depth ≤ 3 mm; O'Leary plaque index $< 20\%$. Exclusion criteria: poor oral hygiene; Cairo classification II/III gingival recession; compromised immune system, systemic diseases, or intake of medications; allergy to antibiotics or other medications to be prescribed; pregnancy or breastfeeding in women; presence of parafunctional habits (bruxism or clenching); history of periodontal surgery over the past 12 months; carious cervical lesions; external root resorption; smoking.

Intervention groups

Soft and hard tissue augmentation around teeth using an allogenic grafting material and a xenogeneic collagen matrix.

Main outcome variables

Tooth position, probing depth, bleeding on probing, plaque index, gingival thickness, gingival recession, vestibular depth.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190712044177N2**

Registration date: **2021-10-25, 1400/08/03**

Registration timing: **prospective**

Last update: **2021-10-25, 1400/08/03**

Update count: **0**

Registration date

2021-10-25, 1400/08/03

Registrant information

Name

Mahdi Kadkhodazadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8803 2208

Email address

mahdi.sbm@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-01, 1400/08/10

Expected recruitment end date

2022-03-01, 1400/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Periodontal phenotype modification in orthodontic patients

Public title

Periodontal tissue thickness in orthodontics

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

≥18 years of age Thin periodontal phenotype Absence of gingival inflammation Probing depth ≤ 3 mm O'Leary plaque index < 20%

Exclusion criteria:

Poor oral hygiene Cairo classification II/III gingival recession Compromised immune system, systemic diseases, or intake of medications Allergy to antibiotics or other medications to be prescribed Pregnancy or breastfeeding in women Presence of parafunctional habits (bruxism or clenching) History of periodontal surgery over the past 12 months Carious cervical lesions External root resorption Smoking

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**
More than 1 sample in each individual
Number of samples in each individual: **10**
Augmented teeth are the samples in each individual.

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Daneshjoo Blv., Evin, Shahid Chamran Hwy

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2020-02-01, 1398/11/12

Ethics committee reference number

IR.SBMU.DRC.REC.1398.217

Health conditions studied

1

Description of health condition studied

Thin periodontal phenotype in orthodontic patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Tissue thickness

Timepoint

At least 6 months postoperatively

Method of measurement

Gingival thickness would be measured using a an endodontic spreader placed in the center of a silicone stopper and inserted perpendicularly from the midbuccal point (3 mm apical to the gingival margin) through the soft tissues to reach a hard surface.

Secondary outcomes

1

Description

Probing depth; bleeding on probing; O'Leary plaque index; gingival recession; vestibular depth

Timepoint

At least 6 months postoperatively

Method of measurement

Probing depth would be measured at 4 points (mesial, distal, midbuccal, and midlingual) from the gingival margin to the bottom of the sulcus. Subsequently, a mean value of the measurements would be calculated for each tooth. Bleeding on probing would be recorded within 60 seconds of probing depth measurement. Gingival recession would be measured from gingival margin to the cementoenamel junction. Vestibular depth would be measured from the midbuccal gingival margin to the mucobuccal fold, while a retractor was placed in the mouth and teeth would be in occlusion. The periodontal probe would be held vertically across the vestibule in line with the axis of each tooth.

Intervention groups

1

Description

Intervention group: All patients receive phase I periodontal therapy. In cases that surgery would be performed during orthodontic treatment, active treatment would be interrupted 3 weeks prior to the surgery and be postponed for 4 months following surgical intervention. Patients rinse their mouth with 0.2% chlorhexidine for 1 minute right before local anesthesia administration (20 mg/mL lidocaine with 1:80,000 epinephrine). An intracrevicular incision with a no.15c scalpel would be used to raise a full-thickness flap extended to two adjacent teeth mesiodistally and 5 mm beyond the mucogingival junction (MGJ) apically. Periosteal incisions would be made for passive flap advancement. The facial aspects of the interdental papillae would be deepithelialized with a microblade to allow final positioning of the flap margin coronal to the cemento-enamel junction (CEJ). The exposed root surfaces would be thoroughly planed with a periodontal curette. Demineralized freeze-dried bone allograft (DFDBA; 500-1000 µm; Iranian Tissue Product Co., Tehran, Iran) would be placed on the bone surface and be covered with a xenogeneic collagen matrix (Mucoderm®, Botiss Biomaterials, Germany). The collagen matrix would be secured with sling sutures (4-0 PLGA, Ethicon, Johnson & Johnson, NJ, USA). Flap closure would be achieved with internal vertical mattress sutures (4-0 Nylon, Ethicon, Johnson & Johnson, NJ, USA) at interdental areas.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahdi Kadkhodazadeh

Street address

Daneshjoo Blvd, Evin, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2240 3075

Email

Intl_office@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2243 9770

Email

Intl_office@sbmu.ac.ir

Web page address

<http://en.sbmu.ac.ir/index.jsp?siteid=256&fkeyid=&siteid=24&pageid=13079&siteid=256>

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

Mahdi Kadkhodazadeh

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Daneshjoo Blvd, Evin, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1983963113

Phone
+98 21 2240 3075
Email
mahdi.sbm@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahdi Kakhodazadeh
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Daneshjoo Blvd, Evin, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2240 3075
Email
mahdi.sbm@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person

Mahdi Kakhodazadeh
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Daneshjoo Blvd, Evin, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2240 3075
Email
mahdi.sbm@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 further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available