

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Periodontal phenotype modification in orthodontic patients: A prospective clinical trial

#### 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:  $\geq 18$  years of age; thin periodontal phenotype; absence of gingival inflammation; probing depth  $\leq 3$  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: **IRCT20190712044177N4**

Registration date: **2023-06-10, 1402/03/20**

Registration timing: **prospective**

Last update: **2023-06-10, 1402/03/20**

Update count: **0**

##### Registration date

2023-06-10, 1402/03/20

##### 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

2023-07-21, 1402/04/30

##### Expected recruitment end date

2023-11-21, 1402/08/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Periodontal phenotype modification in orthodontic patients: A prospective clinical trial

**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**

2023-03-07, 1401/12/16

**Ethics committee reference number**

IR.SBMU.DRC.REC.1402.001

**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

**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.

**2****Description**

Bleeding on probing

**Timepoint**

At least 6 months postoperatively

**Method of measurement**

Bleeding on probing would be recorded within 60

seconds of probing depth measurement.

### 3

#### **Description**

O'Leary plaque index

#### **Timepoint**

At least 6 months postoperatively

#### **Method of measurement**

Dental plaque tablets

### 4

#### **Description**

Gingival recession

#### **Timepoint**

At least 6 months postoperatively

#### **Method of measurement**

Gingival recession would be measured from gingival margin to the cementoenamel junction.

### 5

#### **Description**

Vestibular depth

#### **Timepoint**

At least 6 months postoperatively

#### **Method of measurement**

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 cementoenamel 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**

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##### **Province**

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##### **Postal code**

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##### **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**

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##### **Province**

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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

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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 Kadkhodazadeh

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Person responsible for updating data****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

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**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**

here 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**

Not applicable

**Data Dictionary**

Not applicable