Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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: ≥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 inde; 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
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Iran (Islamic Republic of)
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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
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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 beplaced 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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