Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Evaluation of dimensional changes of periimplant attached gingiva following the treatment of free gingival graft by conventional and Accordion methods; randomized clinical trial two arm parallel

Protocol summary

Study aim

Evaluation of dimensional changes of periimplant attached gingiva following the treatment of Free gingival graft by conventional and Accordion methods

Design

Two arm parallel group randomised clinical trial. The Balanced Block Randomization method will be used to generate a random allocation table. To compare the width of keratinized tissue between two groups 45 samples in each group and in total 90 samples will be studied.To compare the average pain in two groups sample size was considered 21 patient in each group. Phase 2 clinical trial

Settings and conduct

Place of study: Department of Periodontology, Faculty of Dentistry, Tehran University of Medical Sciences and private office After surgery that is performed in one session, day 7 is required for suture removal of donor site and day 14 for suture removal of recipient site. Patients should be referred for 1, 3, and 6 months after surgery to evaluate the outcome of the graft.

Participants/Inclusion and exclusion criteria

Inclusion criteria:(1)More than one implant (with minimum mesiodistal length 15 mm). (2)The width of the keratinized tissue should be less than two mm. Exclusion criteria:(1) systemic disease affecting periodontal conditions and wound healing (2) signs of inflammation (3) bleeding during probing (4)Secretion of pus and active infection

Intervention groups

For the intervention group, graft 60% of the mesiodistal length of recipient site is obtained and in comparison group graft with a suitable length (as far as the recipient site) is prepared. The graft is removed with a minimum thickness of 1.5 mm and a width of 5-7 mm, and the grafts are sutured in the recipient's area.

Main outcome variables

The width of the keratinized tissue, the depth of the vestibule, the probing depth, plaque index and bleeding during probing are measured.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190721044296N1**
Registration date: **2019-11-27, 1398/09/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-27, 1398/09/06**
Update count: **0**

Registration date

2019-11-27, 1398/09/06

Registrant information

Name

Niusha Namadmalian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-06, 1398/06/15

Expected recruitment end date

2020-03-05, 1398/12/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of dimensional changes of periimplant attached gingiva following the treatment of free gingival graft by conventional and Accordion methods; randomized clinical trial two arm parallel

Public title
periimplant free gingival graft
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
More than one implant (with min. mesiodistal length 15 mm). The width of the keratinized tissue should be less than 2 mm.
Exclusion criteria:
Systemic disease affecting periodontal conditions and wound healing Signs of inflammation Bleeding during probing Secretion of pus and active infection
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **21**
More than 1 sample in each individual
Number of samples in each individual: **2**
2 adjacent implant in each person
Randomization (investigator's opinion)
Randomized
Randomization description
A random allocation list is provided by a collaborator of the methodology and project statistics. Examination of patients for the eligibility of patients is done by the periodontist specialist of the faculty. Patients receive the questionnaire and numbered envelopes in the same order of enter to the study by the executor (resident of periodontology) and thus assigned to two treatment groups. Envelopes are opened precisely before surgery and in accordance with the surgical procedure outlined therein.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Dentistry Faculty of Medical Sciences, Amirabad, North kargar street
City
Tehran
Province
Tehran
Postal code
1343856134
Approval date
2019-07-09, 1398/04/18
Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1398.071

Health conditions studied

1

Description of health condition studied
mucogingival problem around implant, deficiency in thickness and width of keratinize tissue
ICD-10 code
K13.22
ICD-10 code description
Minimal keratinized residual ridge mucosa

Primary outcomes

1

Description
"Width of the keratinized tissue"
Timepoint
evaluating Width of the keratinized tissue 1, 3, and 6 months after surgery.
Method of measurement
As with similar studies, the reference point for measuring the width of the keratinized tissue is gingival margin in the central region of the implant. The width of the keratinized tissue is measured by doing the roll test and measuring the distance with the Michigan Probe to the mucogingival Line.

2

Description
"Vestibular Depth"
Timepoint
evaluating Vestibular Depth 1, 3, and 6 months after surgery.
Method of measurement
As with similar studies, the reference point for measuring the Vestibular Depth is gingival margin in the central region of the implant. Vestibular depth is measured by

measuring the margin of the gingiva in the central region of the implant with the Michigan O probe to the depth of the vestibule.

3

Description
"probing depth"
Timepoint
evaluating probing depth 1, 3, and 6 months after surgery.
Method of measurement
The probing depth is measured as the penetration of the probe into the sulcus around the implant with the Michigan O probe.

4

Description
"Plaque index"
Timepoint
evaluating Plaque index 1, 3, and 6 months after surgery.
Method of measurement
The amount of plaque is recorded according to the Silness & Loe index. In this index, the score is zero for the absence of microbial plaque, the score of one corresponding to the presence of a thin layer of plaque that is characterized by moving the probe on the margin of the free gingiva. If there is a moderate amount of plaque visible to the naked eye, it is awarded a score of 2 and if there is a large accumulation of a score of 3.

5

Description
"bleeding on probing"
Timepoint
evaluating bleeding on probing 1, 3, and 6 months after surgery.
Method of measurement
Bleeding during probing is recorded as the presence or absence of bleeding during probing.

6

Description
"pain"
Timepoint
Pain is measured daily after surgery until total removal of pain.
Method of measurement
After surgery, the pain is recorded using a Numerical rating scale. The patient is asked to record daily pain levels until the pain is eliminated. Zero refers to the absence of pain and the number 10 refers to the worst pain experienced by the patient.

7

Description
"The amount of shrinkage"
Timepoint
evaluating the amount of shrinkage 1, 3, and 6 months after surgery.
Method of measurement
Ratio of Shrinkage Percentage of Keratinized Tissue Width in each Specimen at Time Intervals

Secondary outcomes

empty

Intervention groups

1

Description
“Intervention group one”: For treatment with Accordian method, tissue with 60% mesiodistal length of the recipient area is provided.The graft is removed with a minimum thickness of 1.5 mm and a width of 5-7 mm and are sutured to the recipient area.
Category
Treatment - Surgery

2

Description
Intervention group two: conventional free gingival graft. In Conventional method graft with appropriate length (the size of the recipient site) is made.The graft is removed with a minimum thickness of 1.5 mm and a width of 5-7 mm and are sutured to the recipient area.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Dentistry faculty, Tehran University of Medical Science
Full name of responsible person
Niusha Namadmalian Esfahani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Niusha Namadmalian Esfahani
Position
Resident
Latest degree
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Person responsible for updating data

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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
there is no further 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