Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

Comparative evaluation of root coverage with connective tissue graft associated with coronally advanced flap or vestibular incision subperiosteal tunnel access- Randomizes clinical trial

Protocol summary

Study aim

The aim of the present study will to examine the clinical performance of the connective tissue graft associated with coronally advanced flap (CAF) versus the vestibular incision subperiosteal tunnel access (VISTA).

Design

The present study will design as a single center, randomized, double blind, parallel arm clinical trial of 6 months in duration

Settings and conduct

The patients will be randomly assigned to one of the study groups with computer generated randomization list by another investigator.The random allocation sequence will hand to the investigator who performed all of the surgical procedures on the day of surgery.

Participants/Inclusion and exclusion criteria

Study population include 24 healthy nonsmoking patients (12 in each group) with grade I or II Miller gingival recession. All of the patients are requeste treatment for aesthetic reasons and/or dentin hypersensitivity of exposed roots. Inclusion criteria to study: multiple gingival recession in anterior region of mandible; systemically healthy with no contraindications for periodontal surgery; presence of a minimum of two adjacent periodontal recessions of Miller Class I or II; aged between 18to 65; no need for orthodontic treatment; no caries or restorations on desired teeth. Exclusion criteria of study: systemic conditions or diseases affecting periodontal health such as uncontrolled diabetes, immunodeficiency diseases and local or systemic bone disease; pregnancy or lactation; substance abuse, smoking; use of immunosuppressive or anticoagulant drugs.

Intervention groups

Coronally advanced flap (CAF). Vestibular incision subperiosteal tunnel access (VISTA).

Main outcome variables

At baseline and at 3 and 6 months post-surgically, the following measurements will record for each treated site: pocket probing depth; recession height; recession width; keratinized tissue width; clinical attachment level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200804048305N1**
Registration date: **2020-09-01, 1399/06/11**
Registration timing: **retrospective**

Last update: **2020-09-01, 1399/06/11**
Update count: **0**

Registration date

2020-09-01, 1399/06/11

Registrant information

Name

Zohreh Afshari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5570

Email address

z.afshar90@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-06, 1399/05/16

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of root coverage with connective tissue graft associated with coronally advanced flap or vestibular incision subperiosteal tunnel access- Randomizes clinical trial

Public title

Root coverage with CAF or VISTA

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Multiple gingival recession in anterior region of mandible Systemically healthy with no contraindications for periodontal surgery No need for orthodontic treatment No caries or restorations on desired teeth

Exclusion criteria:

Systemic conditions or diseases affecting periodontal health, pregnancy or lactation Substance abuse, smoking Use of immunosuppressive or anticoagulant drugs

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to one of the study groups with computer generated randomization list.The random allocation sequence will handed to the investigator who performed all of the surgical procedures on the day of surgery.

Blinding (investigator's opinion)

Double blinded

Blinding description

Except the surgeon all of researchers (investigator, outcome assessor, data analyzer) and participants are blind about the procedure

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Hezar Jarib street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2019-09-29, 1398/07/07

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.141

Health conditions studied

1

Description of health condition studied

Gingival recession

ICD-10 code

K06.0

ICD-10 code description

Gingival recession

Primary outcomes

1

Description

Root coverage percentage

Timepoint

Base line, 3 months and 6 months later

Method of measurement

Periodontal probe

2

Description

Complete root coverage

Timepoint

Base line, 3 months and 6 months later

Method of measurement

Periodontal probe

Secondary outcomes

1

Description

Pocket probing depth

Timepoint
Base line, 3 months and 6 months later
Method of measurement
Periodontal probe

2

Description
Clinical attachment level
Timepoint
Base line, 3 months and 6 months later
Method of measurement
Periodontal probe

3

Description
Keratinized tissue width
Timepoint
Base line, 3 months and 6 months later
Method of measurement
Periodontal probe

4

Description
Recession width
Timepoint
Base line, 3 months and 6 months later
Method of measurement
Periodontal probe

5

Description
Recession depth
Timepoint
Base line, 3 months and 6 months later
Method of measurement
Periodontal probe

Intervention groups

1

Description
Intervention group:The VISTA approach begins with a vestibular access incision using 15c scalpel blade. Two vertical incisions will made on both sides of recession area . This is continues at the base of the gingival papillae without affecting their entirety. A microsurgical periosteal elevator (VISTA 1, Dowell Dental Products) will use to create the subperiosteal tunnel with sufficient extension. An elevator with bayonet curves (VISTA 2 and 3, Dowell Dental Products) facilitates access to the gingival sulcus and interproximal areas .The CTG was guided using a horizontal mattress suture within the tunnel by inserting a 3-0 silk suture with a 26-mm 3/8 circle needle. The CTG and mucogingival complex will then advance coronally and stabilize in the new position with a coronally anchore suturing technique using a 6.0 polypropylene suture.
Category
Treatment - Surgery

2

Description
Control group: Two bevelled oblique, slightly divergent, incisions starting at the end of the two horizontal incisions of the distal and mesial teeth and extending to the alveolar mucosa. All of incisions will made with a 15c scalpel blade.The resulting trapezoidal-shaped flap was elevated with in the coronal–apical direction up to exposing 3–4mm of bone apical to the bone dehiscence. The CTG is sutured at the recession area with horizontal double mattress using 6.0 polypropylene suture at the level of buccal CEJ.The gingival margin will advance coronally to the most coronal level of the interproximal papillae.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan University of Medical Sciences, School of Dentistry
Full name of responsible person
Mehrnegar Mahmudzadeh
Street address
Hezarjareeb street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 5570
Email
mehrnegaar@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Nakisa Torabinia
Street address
Hezarjareeb street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 5512

Email
Torabinia@dnt.mui.ac.ir
Grant name
Grant code / Reference number
398110
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Zohreh Afshari
Position
post graduate student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
Hezar jareeb street
City
Isfahan
Province
Isfehan
Postal code
8146773461
Phone
+98 31 3792 5570
Email
Z.afshar90@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Jaber Yaghini
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Hezarjareeb street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 5570
Email
J_yaghini@dnt.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zohreh Afshari
Position
Postgraguat student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
Isfahan University of Medical Science Hezar jarib St. Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 5570
Fax
Email
z.afshar90@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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

Title and more details about the data/document

all data

When the data will become available and for how long

6 month after publication

To whom data/document is available

all people

Under which criteria data/document could be used

systematic review analysis

From where data/document is obtainable

Dr. Mogharehabed Mogharehabed@dnt.mui.ac.ir

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

-

Comments