# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

21 Jun 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**

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**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
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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**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
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Zohreh Afshari
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post graduate student
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## Person responsible for updating data

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## 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**

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**Comments**