Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical comparison of coronally advanced flap plus amniotic membrane seeded with whartons' jelly mesenchymal stem cells and subepithelial connective tissue graft in the treatment of single Miller's class I and II gingival recessions

Protocol summary

Study aim

compare Coronally Advanced Flap plus acellular human amniotic membrane seeded by human Whartons Jelly Stem Cellس with Connective Tissue Graft in the treatment of Miller’s class I and II gingival recessions

Design

A blinded randomized clinical trial with two parallel group each contains 10 patients; Block randomization is computer-generated by the study statistician

Settings and conduct

A periodontics resident in Periodontics Department of Shiraz Dental School does all of the surgeries.A single examiner blinded to the study design and grouping records all the pre- and post surgical measurements.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged ≥۱۸ years; at least one tooth with buccal Miller class I or II recession defects ≥ ۲ mm deep and ≥ ۲mm wide in premolar, canine or incisor area, probing depths ≤۴ mm ; ≥ ۲ mm keratinized tissue; only one tooth at each side acts as a test or control tooth Exclusion criteria: who have a history of cancer or HIV; have an uncontrolled systemic disease with compromised healing potential; using medications known to cause gingival enlargement and anticoagulants INR> ۲.۵; taking medications known to affect bone metabolism; who fail to maintain good plaque control; have Class V restorations extending to root surfaces; have teeth with extremely prominent root surfaces; have a history within the previous 6 months of use of smoking; females who are pregnant or lactating; history of surgical periodontal treatment of the involved site; severe malposition or open contacts; current or planned orthodontic treatment during the course of the study

Intervention groups

coronally advanced flap plus Acellular Amniotic Membrane seeded by human wharton's jelly stem cells/coronally advanced flap plus connective tissue graft

Main outcome variables

Recession Depth and Width; CAL; PD; Keratinized Tissue Height and Thickness; plaque score; Gingival Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210330050791N1**
Registration date: **2021-07-21, 1400/04/30**
Registration timing: **retrospective**

Last update: **2021-07-21, 1400/04/30**
Update count: **0**

Registration date

2021-07-21, 1400/04/30

Registrant information

Name
Maryam Sabet

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3830 2141

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mahsasabet86@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-24, 1400/02/04

Expected recruitment end date

2021-05-19, 1400/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical comparison of coronally advanced flap plus amniotic membrane seeded with whartons' jelly mesenchymal stem cells and subepithelial connective tissue graft in the treatment of single Miller's class I and II gingival recessions

Public title

Assesment of the Effectiveness of Amniotic Membrane Seeded by Whartons' Jelly Stem Cells plus Coronally Advanced Flap for the Treatment of Gingival Recession

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18 or more Patients who have read, understood, and signed an informed consent form Patients who have been able and willing to follow study procedures and instructions Patients who have at least one tooth with buccal Miller class I or II recession type defects Recessions with ≥ ۲ mm depth and ≥ ۲mm width in premolar, canine or incisor area, with probing depths ≤۴ mm and ≥ ۲ mm keratinized tissue Treating only one tooth at each side as a test or control tooth in case of adjacent teeth with recession defects

Exclusion criteria:

ůbjects who are participating in other clinical trials Subjects who have a history of cancer or human immunodeficiency virus Subjects who have an uncontrolled systemic disease with compromised healing potential (such as diabetes mellitus with a recent HbA۱c > ۷%) Using medications known to cause gingival enlargement and anticoagulants with International Normalized Ratio (INR) > ۲.۵ and taking herapeutic doses of medications known to affect bone metabolism Those who fail to maintain good plaque control Teeth with extremely prominent root surfaces Teeth with Class V restorations extending to root surfaces Subjects who have any systemic acute infections in the areas intended for surgery Female subjects who are pregnant or lactating History of surgical periodontal treatment of the involved site Severe tooth malposition or open contacts Current or planned orthodontic treatment during the ۳-month course of the study Molars; teeth with axial mobility; teeth with interproximal loss of attachment; teeth with crowns or veneers causing an undetectable CEJ Patients with a frenum and/or muscle attachment encroaching on marginal gingiva in the first ۶ weeks after frenectomy procedure History of weekly or more frequent use of smokeless chewing tobacco, pipe or cigar smoking and cigarette smoking within the previous ۶ months

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization(block size=2) is computer-generated by the study statistician and the treatment assignments sequentially will be delivered to the operating surgeon for implementation. All pre- and postoperative clinical measurements will be made by a single, masked examiner who is not the operating surgeon and is blinded to the study design and grouping.

Blinding (investigator's opinion)

Double blinded

Blinding description

After explaining the study and tratment procedures for patients completely and acceptance for participating in the study the allocating group for each one is concealed. All pre- and postoperative clinical measurements will be made by a single, masked examiner who is not the operating surgeon and is blinded to the study design and grouping . Finally the study statistician will analyse the data without knowing what treatment is used for each group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committee of Shiraz University of Medical Sciences

Street address

No. 303, Navvab safavi 3/2 Alley, Baghe hoz Blvd

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Shiraz

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Fars

Postal code

7175975561

Approval date

2021-06-13, 1400/03/23

Ethics committee reference number

IR.SUMS.REC.1400.233

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
recession depth: distance between CEJ and gingival zenith
Timepoint
at start point and 3 months after surgery
Method of measurement
measured with standard periodontal probe (williams probe)

2

Description
recession width: the width of the recession defect at the level of CEJ
Timepoint
at start point and 3 months after surgery
Method of measurement
measured with standard periodontal probe (williams probe)

3

Description
clinical attachment loss: the length from the CEJ to the depth of the pocket base
Timepoint
at start point and 3 months after surgery
Method of measurement
measured with standard periodontal probe(williams probe) in mesial,distal and buccal surfaces of tooth

4

Description
probing depth: distance from gingival margin to the base of the sulcus or pocket
Timepoint
at start point and 3 months after surgery
Method of measurement
measured with standard periodontal probe(williams probe) at mesial, distal and buccal side of the tooth

5

Description
keratinized tissue height: height of keratinized tissue from the free gingival margin to the mucogingival junction
Timepoint
at start point and 3 months after surgery
Method of measurement
measured with standard periodontal probe(williams probe)

6

Description
keratinized tissue thickness: the thickness of keratinized tissue measured from outer surface of buccal keratinized tissue to the buccal surface of the tooth
Timepoint
at start point and 3 months after surgery
Method of measurement
determined ۱.۵mm apically to the gingival margin on the central point of the buccal surface, using a number ۱۵ endodontic file with an endodontic stop

Secondary outcomes

1

Description
O´Leary plaque score: The presence of supra gingival plaque on all four tooth surfaces
Timepoint
at base time and 3 months after surgery
Method of measurement
The plaque is disclosed. The presence or absence of plaque is recorded in a simple chart. The plaque incidence in the oral cavity is expressed as an exact percentage.

2

Description
gingival index: The gingival index records gingival inflammation on facial, lingual, mesial and distal sites if teeth
Timepoint
at base time and 3 months after surgery
Method of measurement
Grade0: Normal gingiva Geade1: Mild inflammation Grade2: Moderate inflammation Grade3: Severe inflammation

3

Description
The subject’s perception of pain/discomfort: The amount of pain/discomfort that the patients experience because of exposed root surfaces and shows the amount of root hypersensitivity.
Timepoint
at base time and 3 months after surgery
Method of measurement
visual analogue scale (۰: no pain/discomfort ۱۰:severe pain/discomfort)

Intervention groups

1

Description
Intervention group: coronally advanced flap plus amniotic membrane seeded with whartons jelly mesenchymal stem for root coverage of single Millers class I and II gingival recessions
Category
Treatment - Surgery

2

Description
Control group: coronally advanced flap plus connective tissue graft for root coverage of single Millers class I and II gingival recessions
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Dentistry of Shiraz University of Medical Sciences
Full name of responsible person
Maryam Sabet
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No. 303, 3/2 Navvab Safavi Ave., Bagh Hoz Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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Research Assitant Office, Dental School, Ghasrdasht St.
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7195615878
Phone
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Email
Denth_pazho@sums.ac.ir
Web page address
https://dental.sums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Sabet
Position
Periodontics Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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No. 4, 2nd floor, 2019 Building, No. 6 Alley, Khalili Ave.
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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All patient information that is effective in the result of the study and variables that are recorded before and after surgery will be published as part of the study.

When the data will become available and for how long

Start of the access from the time the results are published

To whom data/document is available

All people who are eager to further research on this issue

Under which criteria data/document could be used

In order to use the information in review articles and further research and study on this subject, the information will be provided to the applicant after authentication.

From where data/document is obtainable

Contact Dr. Maryam Sabet as the researcher and author of this research via email address: mahsasabet86@yahoo.com

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

After proving the identity of the applicant and explaining the reason for the need for data, the information will be emailed to him in PDF format.

Comments