Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Culture of human gingival fibroblasts on an autologous scaffold and evaluation of its effect on augmentation of attached gingiva in comparison with the periosteal fenestration technique in patients with inadequate attached gingiva in a pilot clinical trial

Protocol summary

Summary

The aim of this study is to evaluate the effect of culture of human gingival fibroblasts on an autologous scaffold on attached gingival augmentation. The patients entered in this study should have at least two non-adjacent tooth with an insufficient zone of attached gingiva that required soft tissue grafting . under local anesthesia, a small biopsy 3*2 mm will be prepared from the attached gingiva of the patient. fibroblasts prepared from this biopsy will be added to PRGF prepared from the patient blood to produce a cultured gingival graft. with throwing a coin, control and interventional sides will be randomly selected . preparation of the bed in both sides is periosteal fenestration. At the test site , the tissue engineered gingival graft will be removed from the sterile package , shaped and adapted to the recipient site. A vaseline gauze in an appropriate size will be placed on the graft surface and then a foil adapted . These components will be fixed with sutures. In control side, the process is similar with interventional side but without using the graft. the results (change in attached and keratinized gingival width and probing depth) will be checked after 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108135305N2**
Registration date: **2013-10-14, 1392/07/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-10-14, 1392/07/22

Registrant information

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Mohammad Mohammadi
Name of organization / entity
Kerman Dental School
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Recruitment status

Recruitment complete

Funding source

Kerman Oral and Dental Diseases Research ; Vice Chancellor for Research, Kerman University of Medical Sciences

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2010-09-23, 1389/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Culture of human gingival fibroblasts on an autologous scaffold and evaluation of its effect on augmentation of attached gingiva in comparison with the periosteal fenestration technique in patients with inadequate attached gingiva in a pilot clinical trial

Public title
Gingival Graft
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: no systemic diseases that contraindicated periodontal surgery ; no medications affecting periodontal surgery ; no pregnancy or lactation ; no periodontal diseases ; no smoking ; full mouth plaque score and full mouth bleeding score < 20% at the time of the surgical procedures ; at least two non-adjacent tooth with an insufficient zone of attached gingiva that required soft tissue grafting . exclusion criteria: full mouth plaque score and full mouth bleeding score > 20% at the time of the surgical procedures
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **4**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
a pilot study, case series

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman Medical Sciences University
Street address
Tahmasbabad Crossover, Researches Center
City
Kerman
Postal code
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
86/96/کا

Health conditions studied

1

Description of health condition studied
gingival disease
ICD-10 code
B99
ICD-10 code description
Other and unspecified infectious diseases

Primary outcomes

1

Description
keratinized gingival width
Timepoint
baseline and after 3 months
Method of measurement
the distance between gingival margin and MGJ , measurment with periodontal probe

2

Description
attached gingival width
Timepoint
baseline and 3 months later
Method of measurement
the distance between MGJ to base of the sulcus, measurment with periodontal probe.

3

Description
probing depth
Timepoint
baseline an 3 months later
Method of measurement
the amount of penetration of periodontal probe into the sulcus

Secondary outcomes

empty

Intervention groups

1

Description
In interventional side, gingival graft (Platelet rich plasma + fibroblasts)
Category
Treatment - Surgery

2

Description
In control side, periosteal fenestration technique
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Periodontics Department, Kerman Dental School

Full name of responsible person
Dr. Mohammad Mohammadi

Street address

City
kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research. Kerman University of Medical Sciences

Full name of responsible person
Dr. Shahravan

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Tahmasbabad Crossover, Researches Center

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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
Vice Chancellor for research. Kerman University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

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Assistant Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty