

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

2013-10-14, 1392/07/22

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

Registrant information

Name

Mohammad Mohammadi

Name of organization / entity

Kerman Dental School

Country

Iran (Islamic Republic of)

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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

86/96/15

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 ,
measurement 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,
measurement with periodontal probe.

3**Description**

probing depth

Timepoint

baseline and 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

Street address

Tahmasbabad Crossover, Researches Center

City

Kerman

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

Name of organization / entity

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Full name of responsible person

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Position

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