Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Eeffect of Topical Erythropoietin on Palatal Wound Healing Subsequent to Free Gingival Graft in patients with insufficient keratinized gingiva. Evaluation of Topical Erythropoietin Application on the Healing Outcome of Gingival Graft Recipient Site; A Randomized Controlled Clinical Trial.

Protocol summary

Study aim
Evaluating the effect of local Erythropoietin(EPO) on palatal wound epithelialization and healing and inflammation in free gingival graft(FGG) recipient site

Design
This is a split-mouth randomized controlled clinical trial on seventeen patients who need FGG for at least two sites in mandible. The patient, the surgeon, the initial and final examiner, and the data analyzer are blinded to the intervention.

Settings and conduct
A standardized 10*15 mm graft is harvested from premolar and first molar area of the hard palate. In the donor site: On the day of surgery and 2 days after surgery, on the test site 1ml of the gel containing 4,000 IU ml-1 EPO and on the donor test site, 2ml gel without EPO is applied on the control site. In the recipient site: Test sides are treated with 1 ml erythropoietin (EPO) 4000 IU and the control sites receive 1 ml of distilled water. After two minutes, the harvested gingival graft is stabilized with synthetic absorbable 4/0 sutures. both sites are then covered with surgical dressing. The outcomes are evaluated on days 7,14,21,28,60,90.

Participants/Inclusion and exclusion criteria
Inclusion criteria : 1) age of 18 years old or above; 2) periodontal health; Exclusion criteria: 1) compromised systemic health, such as diabetes mellitus and immune suppression; 2) consumption of anti-inflammatory or antibiotics during last 3 months; 3) smoking, and 4) O'Leary plaque index>15% after phase I periodontal therapy.

Intervention groups
Application of Gel with or without EPO on test or control sites of palate. application of EPO or stilled water on test or control sites before graft suturing.

Main outcome variables
epithelialization rate in palate healing degree in recipient site inflammation around recipient site

General information

Reason for update
In order to add the second part of the same study, with the same protocol and on the same patients.

Acronym

IRCT registration information
IRCT registration number: **IRCT201201278830N1**
Registration date: **2016-10-22, 1395/08/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-21, 1400/05/30**
Update count: **1**

Registration date
2016-10-22, 1395/08/01

Registrant information

Name
Siamak Yaghobee

Name of organization / entity
Faculty of Dentistry, Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date
2016-10-22, 1395/08/01
Expected recruitment end date
2017-02-19, 1395/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Eeffect of Topical Erythropoietin on Palatal Wound Healing Subsequent to Free Gingival Graft in patients with insufficient keratinized gingiva. Evaluation of Topical Erythropoietin Application on the Healing Outcome of Gingival Graft Recipient Site; A Randomized Controlled Clinical Trial.

Public title
Effects of erythropoietin in palatal wound healing, Effect of Erythropoietin on healing of gingival graft
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
age of 18 years old or above periodontal health; need for gingival graft in order to augment keratinized gingiva in at least two mandibular areas
Exclusion criteria:
Age
From **18 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Balanced block randomization was used to allocate each patient into one of the following categories: - Right side surgery first, treated with distilled water on recipient site and gel without EPO on donor site - Right side surgery first, treated with EPO on recipient site and gel containing EPO on donor site - Left side surgery first, treated with distilled water on recipient site and gel without EPO on donor site - Left side surgery first, treated with EPO on recipient site and gel containing EPO on donor site
Blinding (investigator's opinion)
Triple blinded
Blinding description
The patient, the surgeon, the initial and final examiner, and the data analyzer are blinded to the intervention. To meet the assumptions of randomization, a number of sealed non-transparent coded envelopes are prepared with letters A, B, C, or D printed on them. A third individual opens each envelope and explains the sequence of surgery and gel application to the surgeon.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Tehran University of Medical Science
Street address
North Karegar Street
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Province
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Postal code
14399-55991
Approval date
2014-11-23, 1393/09/02
Ethics committee reference number
9011213001-119225

Health conditions studied

1

Description of health condition studied
palatal wound
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Epithelialization
Timepoint
on days 7, 14 , 21 and 28
Method of measurement
Hydrogen Peroxide 3% application

2

Description
Degree of healing
Timepoint
on days 7, 14,21,28, 60, 90

Method of measurement
Graft color match, contour, and texture

3

Description
Inflammation on recipient site
Timepoint
on days 7, 14,21,28, 60, 90
Method of measurement
based on the size of the red inflammatory halo around the graft

Secondary outcomes

1

Description
Inflammation
Timepoint
on days 7,14,21 and 28
Method of measurement
direct observation of the region, also photographs taken from test and control areas are prepared to be observed by three periodontists

Intervention groups

1

Description
Control group:A 10*15 mm template is used to harvest a graft from premolar and first molar area of the hard palate and is fixed in the recipient site.In control site: After bleeding control in the donor site, the day of surgery and 2 days after surgery 1ml of the hydroxy ethyl cellulose without Erythropoietin is applied on the wound site.To prepare the bed, a split thickness horizontal incision at mucogingival junction (15 mm long) and two vertical incisions at both ends (10 mm long) is made with scalpel blade no. 15. The control sides receive 1 ml of distilled water. After two minutes, the harvested gingival graft is adapted on the site and stabilized with synthetic absorbable 4/0 sutures (Polyglycolate coated; SUPABON, SUPA, Iran). Then the wound sites are covered with a foil and the periodontal pack (coe pak, GC America Co., USA).
Category
Treatment - Drugs

2

Description
Intervention group: A 10*15 mm template is used to harvest a graft from premolar and first molar area of the hard palate and is fixed in the recipient site.After bleeding control in the donor site, the day of surgery and 2 days after surgery 1ml of the hydroxy ethyl cellulose gel containing 4,000 IU ml-1Erythropoietin (pooyesh daroo) is applied on the wound site.Then the wound sites are covered with a foil and the periodontal pack (coe pak, GC America) is placed over them. To prepare the bed, a split thickness horizontal incision at mucogingival junction (15 mm long) and two vertical incisions at both ends (10 mm long) is made with scalpel blade no. 15. Test sides are treated with 1 ml erythropoietin (EPO) 4000 IU (PDpoetin, Pooyeshdarou, Tehran, Iran) . After two minutes, the harvested gingival graft is adapted on the site and stabilized with synthetic absorbable 4/0 sutures (Polyglycolate coated; SUPABON, SUPA, Iran). Then the wound sites are covered with a foil and the periodontal pack (coe pak, GC America Co., USA).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran University of Medical sciences,Dental faculty,Department of Periodontology
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Affairs, Tehran University of Medical Science
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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
Research Affairs, Tehran University of Medical Science

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
Tehran University of Medical Sciences

Full name of responsible person
Siamak Yaghobee

Position
DDS,Periodontist and Implantologist

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
According to the routine process of publications, the data will be presented to the journal if required or every researcher who asks for.

Study Protocol
Yes - There is 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

The first part related to palatal healing has been published. The part related to recipient site is in submission progress. Effect of Topical Erythropoietin (EPO) on palatal wound healing subsequent to Free Gingival Grafting (FGG), Siamak Yaghobee 1, Nina Rouzmeh 1, Hoori Aslroosta 1, Sanaz Mahmoodi 2, Afshin Khorsand 1, Mohamad Javad Kharrazifard 3; Braz Oral Res. 2018 Jun 11;32:e55 Data and photographs will be available if requiered.

When the data will become available and for how long

Part of it has been published. The second part will be accessible after publication.

To whom data/document is available

Every researcher(working at university or not, related to dentistry or not) who receives the article from journal.

Under which criteria data/document could be used

For future studies.

From where data/document is obtainable

From the related journal (which is open access) in which the article is published, the article is free and available.

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

Following the rules of the journal in which the article is published. As the first article is published in an open access journal, the article is available at no charge. The second article will be available the same way when published.

Comments