

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of Cyanoacrylate adhesive on clinical parameters of postoperative wound healing following free gingival graft

Protocol summary

Study aim

The aim of this study was to determine the effect of cyanoacrylate adhesive on the clinical parameters of Postoperative wound healing following free gingival graft

Design

Two arm parallel group, randomized controlled trial with blinding

Settings and conduct

This double blind Randomized control clinical trial was conducted on 15 patients requiring free gingival graft in two quadrants . Each patient's mouth was randomly divided into case and control groups, and in the case group, cyanoacrylate adhesive was applied to the Palate Donor site . In the control group, the donor site was sutured , and the periodontal pack (Coepack) was placed on it.The thickness of the graft must be between 1-1.5 mm and the both sides graft length be the same.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients requiring Free Gingival Graft in two quadrants. Exclusion Criteria: 1) systemic disease 2)Pregnancy 3)The Presence of Painful Conditions in oral cavity such as teeth requiring root canal therapy. 4)smoking , alcohol or drug abuse 5)Surgical History in the last 6 months 6)Trauma

Intervention groups

Each patient's mouth was randomly divided into case and control groups, and in the case group, cyanoacrylate adhesive was applied to the Palate Donor site . In the control group, the donor site was sutured according to the usual method, and the periodontal pack (Coepack)was placed on it.

Main outcome variables

1) pain by VAS scale 2) Healing Scale 3) Measuring the dimensions of wound by photography 4) Epithelialization by H2O2 Application 3% 5) Discomfort scale 6) The presence or absence of delayed and Immediate bleeding 7) The sensitivity disorder 8) Normal feeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120311009260N3**

Registration date: **2019-03-17, 1397/12/26**

Registration timing: **retrospective**

Last update: **2019-03-17, 1397/12/26**

Update count: **0**

Registration date

2019-03-17, 1397/12/26

Registrant information

Name

Mohammad Reza Karimii

Name of organization / entity

Islamic Azad university Dental Branch

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-24, 1397/09/03

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Cyanoacrylate adhesive on clinical parameters of postoperative wound healing following free gingival graft

Public title

Effect of Cyanoacrylate adhesive on wound healing

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients who require free gingival graft in two quadrants

Exclusion criteria:

systemic disease Pregnancy The presence of painful conditions in oral cavity such as teeth requiring root canal therapy smoking , alcohol or drug abuse Surgical history in the last 6 months Trauma

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **2**

All the Patients requiring free gingival graft , the mouth of each patient is randomly divided into case and control group .

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random sampling. Randomization with Computer generated randomization list (Microsoft Excel 2016)

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is single blind , and the patient is blind to the donor site treatment .

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Islamic Azad university tehran Dental Branch

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no 4,9th Neyestan .Pasdaran Street

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Province

Tehran

Postal code

1946853314

Approval date

2018-04-22, 1397/02/02

Ethics committee reference number

IR.IAU.DENTAL.REC.1397.037

Health conditions studied**1****Description of health condition studied**

The wound healing following free gingival graft

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain

Timepoint

After A week , a month and 3 months.

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Epithelialization

Timepoint

After a week , a month and 3 months

Method of measurement

The amount of epithelization is evaluated by the use of H2O2% 3 in the area and the presence or absence of bubbles. If the intact epithelium membrane is formed, H2O2 will not penetrate the area and no bubble will be produced. Therefore, not seeing the bubble after application of H2O2% 3 is a sign of Complete Epithelialization, and if the bubble is seen in more than 2/3 of the area, Mild and Between 1/3 to 2/3 Moderate and less than 1/3 Complete Epithelialization has occurred .

Intervention groups**1****Description**

Intervention group: In the case group after the graft harvetsing , the cyanoacrylate adhesive applied to the donor site .

Category

Treatment - Drugs

2**Description**

In the control group after the graft harvesting, the donor site was sutured and the periodontal pack applied.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Islamic Azad University Tehran dental branch

Full name of responsible person

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Web page address<http://dentaliau.ac.ir/fa>**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

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Full name of responsible person

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Web page address<http://dentaliau.ac.ir/fa>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Dr. Mohammadreza Karimi

Position

Assistant professor, department of periodontology of Islamic Azad University

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Web page address<http://dentaliau.ac.ir/fa>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data including post operation pain , wound healing m
epithelialization and other clinical parameters will be
shared .

When the data will become available and for how long

6 months after publition

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Dental academic groups would be able receive the data
by contacting the research authorities.

From where data/document is obtainable

Dr mohammadreza karimi , m_karimi@dentaliau.ac.ir

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

Authorized letter from scientific organization should be
sent to Tehran dental branch , Islamic Azad University.
Following the approval by authorities , the data will be
released during a period of 6 month.

Comments