

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of wound healing quality and patient comfort by tissue cyanomethacrylate adhesive in comparison with classical suture in the area of free gingival transplantation

Protocol summary

Study aim

Evaluation of wound healing quality and patient comfort by tissue cyano methacrylate adhesive in comparison with classical suture in the area of free gingival transplantation

Design

This study will be a randomized, parallel, single-blind, phase 3 clinical trial. The sample size will be considered 64 people and will be divided into 4 groups using the block randomization method. Stata software and ralloc package will be used to assign participants to study groups.

Settings and conduct

This study will be done on patients referred to a private practice in Ilam city. data analyzer will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 25 to 50 years; Acceptable oral hygiene before surgical treatment; Patients with gingivitis who have a probe depth of 5 mm in three consecutive teeth in at least two quadrants. Exclusion criteria: Patients with known systemic diseases; Drug allergy; Obsessive and mental disorders; smoking; chewing tobacco; Pregnant women

Intervention groups

For the first group, the open wound which created in the palatal, will be sutured with 0-3 silk thread from Supa classic brand and the wound will be closed. For the second group, the open wound which created in the palatal, will be covered by cyanomethacrylate oral adhesive. For this purpose, after the wound, the powder which prepared by GS company will be mixed with the accompanying liquid, and then an oral adhesive will be created and the wound will be covered with this oral adhesive. For the third group, the open wound which created in the palatal, half of it will be sutured with 0-3 silk thread from Supa Classic brand, and the other half will be covered with cyanomethacrylate oral adhesive.

For the fourth group, which is the control group, no intervention will be taken for the open wound.

Main outcome variables

Bleeding index; Pain index; Recovery index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220904055872N1**

Registration date: **2022-09-24, 1401/07/02**

Registration timing: **prospective**

Last update: **2022-09-24, 1401/07/02**

Update count: **0**

Registration date

2022-09-24, 1401/07/02

Registrant information

Name

Zeynab Abdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3223 5024

Email address

avin.abs676@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-07, 1401/07/15

Expected recruitment end date

2022-12-06, 1401/09/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of wound healing quality and patient comfort by tissue cyanomethacrylate adhesive in comparison with classical suture in the area of free gingival transplantation

Public title
Comparison of cyano methacrylate glue and suture in palatal wound healing

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 25 to 50 years Acceptable oral hygiene before surgical treatment Patients with gingivitis who have a probe depth of 5 mm in three consecutive teeth in at least two quadrants
Exclusion criteria:
Patients with known systemic diseases or drug therapy that may interfere with wound healing Drug allergy Obsessive and mental disorders smoking chewing tobacco Pregnant women or mother has given birth

Age
From **25 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the randomization unit is the individual. In order to allocation of people into 4 study groups, the block randomization method will be used. In this way, by considering 8 permutations (2 repetitions for each group in each permutation), the sequence of blocks will be determined. A number will be assigned to each block and then a number will be selected using the random number table and according to the number on the right side of the selected random number, the block should be used, will be determined. Stata software and ralloc package will be used to create the sequences. Since the permutations will be labeled with the random code that assigned by the software, allocation concealment will be applied.

Blinding (investigator's opinion)
Single blinded

Blinding description
Since the wound healing chart will be completed by the periodontist, there will be no possibility of blinding. But considering that the collected information will be coded,

single-blinding will be implemented for the Data analyzer.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ilam University of Medical Sciences

Street address

Ilam town beheshti blvd payam ave tarnian allay

City

Ilam

Province

Ilam

Postal code

6931313119

Approval date

2022-09-03, 1401/06/12

Ethics committee reference number

IR.MEDILAM.REC.1401.087

Health conditions studied

1

Description of health condition studied

palatal wound

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

wound healing index

Timepoint

5 and 7 days after surgery

Method of measurement

examination by periodontist

2

Description

bleeding inindex

Timepoint

5 and 7 days after surgery

Method of measurement

examination by periodontist

3

Description

pain index

Timepoint

5 and 7 days after surgery

Method of measurement

examination by periodontist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the first group, the open wound created in the palate will be sutured with 0-3 silk thread from supa classic suture and the wound will be closed.

Category

Treatment - Other

2

Description

Intervention group: For the second group, the open wound which created in the palate is covered by cyanomethacrylate oral adhesive. For this purpose, after the wound, the powder prepared by GS company will be mixed with the accompanying liquid, and then an adhesive oral adhesive will be created and the wound will be covered with this mater.

Category

Treatment - Other

3

Description

Intervention group: For the third group, the open wound which created in the palate, half of it will be sutured with 0-3 silk thread from supa classic suture, and the other half will be covered with cyanomethacrylate oral adhesive.

Category

Treatment - Other

4

Description

Control group: For the fourth group, which is the control group, no action will be taken for the open wound in the palate.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Abdi's personal office

Full name of responsible person

Zynab Abdi

Street address

Ilam town beheshti blvd payam Ave tarnian allay

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Avin.abs676@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ilam University of Medical Sciences

Full name of responsible person

Abbas Maleki

Street address

Ilam University of Medical Sciences campus,
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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

Ilam 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**

Ilam University of Medical Sciences

Full name of responsible person

Fatemeh abbasi

Position

General dentist

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Full name of responsible person

Reza pakzad

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ilam University of Medical Sciences

Full name of responsible person

Zeynab Abdi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Ilam University of Medical Sciences

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

datas that there is no problem to publish them will be published

When the data will become available and for how long

Six months after the results are published

To whom data/document is available

Researchers and students

Under which criteria data/document could be used

Doing research work

From where data/document is obtainable

Fatemeh abbasi Avin.abs676@gmail.com

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

It will be sent to the person's email address for a maximum of one month

Comments