

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of the photodynamic therapy with Nano-emodin on palatal wound healing after free gingival graft; a parallel clinical trial

Protocol summary

Study aim

Determining the clinical effect of photodynamic therapy with nano-emodin on palatal wound healing after free gum graft surgery.

Design

This study will be conducted as a controlled, triple double and parallel clinical trial on 51 patients. after graft harvesting, The patients will be randomly using a computerized block randomization process divided into three groups.

Settings and conduct

The study will be conducted in the Department of Periodontology, Faculty of Dentistry, Tehran University of Medical Sciences. Patients will be randomly divided into three groups receiving gel containing nano-emodin alone, group receiving gel containing nano-emodin and photodynamic therapy and control (receive placebo without radiation). Patients, clinical examiners and epidemiologists were blind to the study.

Participants/Inclusion and exclusion criteria

Patients over 18 years of age and systemically healthy that they need free gingival graft with a maximum width of 10 mm and a length of 15 to 25 mm were included in the study. smokers, take medications, or have conditions that interfere with wound healing were excluded from the study.

Intervention groups

After harvesting the graft from the palatal, the patients were divided into three groups, in the two test groups, nano-emodin gel was applied for 5 minutes with and without LED laser radiation to the effect of photodynamic therapy, on the palate wound. In the control group, only placebo gel is used, and in all groups, a surgical dressing is placed on the wound.

Main outcome variables

Investigate the amount of epithelialization by 3% hydrogen peroxide Measurement of the remaining wound area using ImageJ software Measurement color matching with Photoshop using standard photographs The amount

of pain based on the VAS scale and the presence or absence of bleeding in the first 11 days after surgery through a questionnaire by the patient

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221212056791N1**

Registration date: **2023-01-08, 1401/10/18**

Registration timing: **prospective**

Last update: **2023-01-08, 1401/10/18**

Update count: **0**

Registration date

2023-01-08, 1401/10/18

Registrant information

Name

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of the photodynamic therapy with Nano-emodin on palatal wound healing after free gingival graft; a parallel clinical trial

Public title
Effect of Nano-emodin on palatal wound healing

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients age ≥ 18 years. systemically healthy. The graft dimensions were taken with a maximum width of ten millimeters and a length of fifteen to twenty-five millimeters. Patients should sign the informed consent form to participate in the study after receiving sufficient information about the risks, advantages and disadvantages.
Exclusion criteria:
Active gag reflux. Smoking and alcohol consumption, periodontal diseases, traumatic occlusion systemic diseases considered either as the contra-indications of periodontal surgeries or in contradiction with wound healing process such as diabetes and history of treatment with high dose steroids taking anti-coagulation medications, radiotherapy or other types of therapies suppressing the immunity system, pregnancy, breast-feeding, digestive disorders. a history of taking medications distorting the wound healing process or inducing gingival enlargement. the patients missing the follow-up sessions after the surgery.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
0

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **51**

Randomization (investigator's opinion)
Randomized

Randomization description
After graft harvesting, the patient was randomly assigned into one of the three groups of treatment using a randomization software. Random allocation, patient enrolment, and assignment was done by different clinicians. An epidemiologist who was not aware of the treatment modalities generated the random allocation sequence using a computerized block randomization process.

Blinding (investigator's opinion)
Triple blinded

Blinding description

To be blind, the examiners were asked to comment only on the final outcome and then their comments were recorded. Statistical analysis was done in three groups A, B and C so that the analyzer is blind to the results. A placebo gel was used in the control group to make the patient blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

At the end of North Kargar Street, before Hakim Highway, Faculty of Dentistry

City

Tehran

Province

Tehran

Postal code

1439955991

Approval date

2022-09-05, 1401/06/14

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1401.086

Health conditions studied

1

Description of health condition studied

Evaluation of palatal wound healing after free gingival graft surgery due to lack of attached gingiva

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The clinical effect of photodynamic therapy using Nano-Emodin on the palatal wound healing after free gingival graft surgery.

Timepoint

Comparison of the average area of the remaining wound in the palate at intervals of 7, 14, 21 and 28 days after surgery. Comparison of the amount of bleeding after surgery in the first 7 days. Comparison of the degree of color matching and epithelialization in the time interval

7, 14, 21, 28. Comparison of the average index of pain and discomfort in the first 10 days after surgery

Method of measurement

The average area of the remaining wound in the area by image j program. Comparison of the amount of bleeding through a questionnaire. Comparison of color matching with Adobe Photoshop software. Examining the amount of epithelialization through 3% hydrogen peroxide. Index of pain and discomfort using Visual Analogue Scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Placing a gel containing 10% Nano-Emodin for 5 minutes on the wound surface

Category

Treatment - Drugs

2

Description

Intervention group: Placing a gel containing 10% Nano-Emodin for 5 minutes on the wound surface along with LED radiation for 1 minute

Category

Treatment - Drugs

3

Description

Control group: Placing placebo gel without LED radiation

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontics, Faculty of Dentistry,
Tehran University of Medical Sciences

Full name of responsible person

Siamak yaghobee

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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

medical University Tehran

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

Mahdi Isaabadi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Gathered data will be analyzed and then published.

When the data will become available and for how long

It will be determined after the article is published.

To whom data/document is available

Everyone (depending on the journal policies)

Under which criteria data/document could be used

Published article will be public.

From where data/document is obtainable

The journal that the paper is published in.

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

Just sending Email to corresponding author.

Comments