Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical evaluation of the efficacy of nano-emul gel of Atorvastatin on the healing of wounds after periodontal flap surgery (double-blinded randomized clinical trial)

Protocol summary

Study aim

Clinical evaluation of the efficacy of nano-emulgel of Atorvastatin on the healing of wounds after periodontal flap surgery double-blinded randomized clinical trial.

Design

Patients referred to the Department of Periodontics Faculty of Dentistry, Tabriz University of Medical Sciences. Sample size: 50 patients diagnosed with periodontitis and indicated for periodontal flap surgery.

Settings and conduct

After preparing the nanoemulsion of atorvastatin gel by primary emulsion and after passing through electron microscopy and spectroscopy, the gel is placed in the flap area and the amount of pain and swelling of soft tissue, gum color, pocket probe depth, clinical attachment loss, bleeding index, plaque index in the two areas of the combination used will be examined with the control area on patients who are candidates for periodontal flap surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: In general, have a good health status - Be available during the 12-week study. Patients who are not smokers. Suffer from periodontitis and require periodontal surgery. Exclusion criteria: Pregnant women - People who have used antibiotics and anti-inflammatory drugs within a month before surgery - Patients use orthodontic appliances. People with removable dentures - People with intraoral pathological conditions - People who have had an allergic reaction to healthcare products

Intervention groups

In this study, the surgical area in the patient's mouth is randomly assigned to two groups. The intervention group will receive the study material, while the control group will not. This setup aims to compare outcomes between treated and untreated areas.

Main outcome variables

Soft tissue swelling, gum color, probe pocket depth, clinical attachment loss, bleeding index, plaque index, pain experienced, type of pain, number of analgesics used, gingival bleeding.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241227064183N1**
Registration date: **2025-02-06, 1403/11/18**
Registration timing: **prospective**

Last update: **2025-02-06, 1403/11/18**
Update count: **0**

Registration date

2025-02-06, 1403/11/18

Registrant information

Name

Mohammadreza Hariri

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-15, 1403/11/27

Expected recruitment end date

2025-07-22, 1404/04/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical evaluation of the efficacy of nano-emul gel of Atorvastatin on the healing of wounds after periodontal flap surgery (double-blinded randomized clinical trial)

Public title
Clinical evaluation of the efficacy of nano-emul gel of Atorvastatin on the healing of wounds after periodontal flap surgery (double-blinded randomized clinical trial)
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients will be included in the study if they are: aged 18-75 years, in good general health, non-smokers, available during the 12-week study, have periodontitis, as defined by at least two non-adjacent interproximal sites with pocket depths (PPDs) greater than 4 mm or other radiographic evidence such as visible alveolar bone loss, and require periodontal surgery.
Exclusion criteria:
Exclusion criteria: Pregnant women, lactating women, patients who have used antibiotics and anti-inflammatory drugs within 1 month before surgery, patients whose systemic disease has directly affected their periodontal disease (such as chronic use of steroids, bisphosphonates, calcitonin, methotrexate, and estrogens in the past 6 months), patients with removable restorations, patients using removable orthodontic appliances, periodontal treatment in the past year, patients who have participated in another study within the past 1 month, patients who have had allergic reactions to hygiene products, patients who are prohibited from eating or drinking fluids for 4 hours due to medical conditions, patients with 5 or more decayed teeth.
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
1
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
n this study, 25 intervention and 25 control envelopes, which were completely identical in appearance, were randomly numbered (from 1 to 50). The allocation sequence was generated by the research assistant using Random Allocation Software (RAS). Each envelope was opaque, sealed, and remained closed until the start of treatment. The distribution of envelopes to patients was done in no particular order and completely randomized. The preparation of envelopes according to the allocation sequence was performed by a person not involved in the treatment process to avoid bias. Patients were matched by age and sex, and this design was done to increase the accuracy and generalizability of the results.
Blinding (investigator's opinion)
Double blinded
Blinding description
For blinding, a sealed envelope will be used and the sealed envelope will be given to the doctor by the patient. In other words, after opening the envelope, the doctor will use atorvastatin nano-emul gel for the wound or will be considered as a control group. Also, the study will be double-blind and the student evaluator and the patient will not know about the case and control areas.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Research development and coordination center (RDCC), faculty of medicine, Tabriz university of medical sciences, Attar Neyshaburi St., Golgasht, St. Azadi St.
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Tabriz
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East Azarbaijan
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5166/15731
Approval date
2024-12-10, 1403/09/20
Ethics committee reference number
IR.TBZMED.REC.1403.759

Health conditions studied

1

Description of health condition studied
Wounded tissue caused by periodontal flap surgery
ICD-10 code
T81.3
ICD-10 code description
Disruption of wound, not elsewhere classified

Primary outcomes

1

Description
Clinical variables evaluated after surgery include soft tissue swelling, gum color, pocket probe depth, clinical attachment loss, bleeding index, plaque index. Also, during the first 7 days after surgery, patients will complete a questionnaire to evaluate post-surgery complaints, which includes the amount of pain experienced, the type of pain, the number of painkillers taken, swelling of the mucous membrane and swelling of the face, and swelling and bleeding of the gum.

Timepoint
Examining the results of wound healing 1, 4 and 8 weeks following the surgery

Method of measurement
To assess the degree of swelling, the number 0 will be used for no swelling, the number 1 for moderate swelling, and the number 2 for significant swelling. To assess the color of gingiva, in comparison with the opposite side, the numbers 0 for no redness, 1 for moderate redness, and 2 for significant redness will be used. For measuring the depth of the pocket probe and CAL, the reference of these measurements will be from the CEJ. Bleeding index will be measured at 6 levels of the involved teeth and finally a numerical measure will be presented as an average. The presence or absence of bleeding during probing will be recorded with two scales: 0 for no bleeding and 1 for bleeding that is seen between 0 and 30 seconds after probing. The presence or absence of plaque will also be measured with the same scale along the gingival margin.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The surgical area in the patient's mouth is randomly selected as the intervention group and the study material will used in this area.

Category
Treatment - Drugs

2

Description
Control group: The surgical area in the patient's mouth is randomly selected as the control group, and the study material will not be used in this area.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dentistry faculty of Tabriz university of medical sciences, department of periodontics

Full name of responsible person
Dr. Masoumeh Faramarzi

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Dentistry Faculty of Tabriz university of medical sciences, Golgasht St., Azadi Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Maryam Kouhsoltani

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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Maryam Kouhsoltani

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Oral & Maxillofacial Pathology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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