Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Title : Evaluation of the effect of photodynamic therapy on coated orthodontic mini-screws with zinc oxide nanoparticles stability, peri-miniscrew gingival condition and patient pain belief: A parallel randomized controlled clinical trial

Protocol summary

Study aim

The aim of this study is to evaluate the effect of photodynamic therapy on the stability of orthodontic mini-screws coated with zinc oxide nanoparticles, peri-miniscrew gingival condition, and patient pain perception.

Design

A randomized, parallel, five-arm clinical trial (including two control groups); block randomization with block size 6 (sequence generated by the study epidemiologist using a six-sided dice and kept in opaque sealed numbered envelopes for allocation concealment), triple-blind, Phase II, total sample size = 60 patients.

Settings and conduct

This clinical trial will be conducted at the School of Dentistry, Iran University of Medical Sciences, on orthodontic patients requiring miniscrews. Miniscrews are inserted in the buccal region by an orthodontist. Only the operator is aware of allocation; patients, sample collectors, outcome assessors, and the statistician are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients (Class II Division I malocclusion) aged 18 to 28 years old periodontally healthy, and requires extraction of the maxillary first premolars and absolute anchorage. Exclusion criteria: Smoking, presence of periodontal disease, systemic diseases.

Intervention groups

Intervention group 1 includes patients receiving coated mini-screws with zinc oxide nanoparticles plus LED irradiation. Intervention group 2 includes patients receiving coated mini-screws with zinc oxide nanoparticles without irradiation. Intervention group 3 includes patients receiving uncoated mini-screws with LED irradiation. Intervention group 4 includes patients receiving uncoated mini-screws without irradiation plus chlorhexidine mouthwash. Intervention group 5 includes patients receiving uncoated mini-screws without irradiation and without mouthwash.

Main outcome variables

Stability of miniscrews TNF-α and IL-1β levels Gingival Index Patient pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250811066814N1**
Registration date: **2025-09-14, 1404/06/23**
Registration timing: **prospective**

Last update: **2025-09-14, 1404/06/23**
Update count: **0**

Registration date

2025-09-14, 1404/06/23

Registrant information

Name
Rashin Bahrami
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2025-10-23, 1404/08/01
Expected recruitment end date
2026-05-22, 1405/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Title : Evaluation of the effect of photodynamic therapy on coated orthodontic mini-screws with zinc oxide nanoparticles stability, peri-miniscrew gingival condition and patient pain belief: A parallel randomized controlled clinical trial

Public title
Laser in Dentisry
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18 to 28 who are periodontally healthy. Require the use of mini-screws for orthodontic treatment. The orthodontic treatment plan for these patients (diagnosed with Class II Division I malocclusion) involves extraction of the maxillary first premolars and requires absolute anchorage.
Exclusion criteria:
Active gag reflex, smoking, presence of periodontal disease, additional forces including mechanical forces from orthodontics and traumatic occlusion, systemic diseases that interfere with tissue healing such as diabetes, treatment with high-dose steroids, radiotherapy, or immunosuppressive therapies, pregnancy, breastfeeding, gastrointestinal problems, and allergy to impression materials. Patients who do not attend regular follow-up visits after mini-screw placement. History of medication use that interferes with healing or causes gingival overgrowth.
Age
From **18 years** old to **28 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization with a block size of 6 and an individual unit of randomization is used. In each block, all interventions are repeated once. The allocation sequence is generated using a six-sided dice by the study epidemiologist. Randomization is non-stratified. For allocation concealment, the final sequence is placed in opaque, sealed, and numbered envelopes, which are opened only at the time of each participant’s enrollment. Only the study epidemiologist is aware of the allocation sequence and is not involved in intervention delivery or data collection.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Only the operator is aware of the allocation. Participants, sample collectors, outcome assessors, and the statistician are blinded to group assignment. All miniscrews (American Orthodontics, USA) are identical in size, shape, and color, and differences related to ZnO coating or LED irradiation are not distinguishable to participants. Therefore, participant-level blinding is feasible. To prevent unblinding during analysis, statistical codes are designed independently from envelope numbers.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences (IUMS), Shahid Hemmat Highway, Tehran, IRAN
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Tehran
Province
Tehran
Postal code
1449614535
Approval date
2025-07-21, 1404/04/30
Ethics committee reference number
IR.IUMS.REC.1404.435

Health conditions studied

1

Description of health condition studied
stability of coated orthodontic mini-screws with zinc oxide nanoparticles , peri-miniscrew gingival condition and patient pain belief
ICD-10 code
-

ICD-10 code description

-

Primary outcomes

1

Description

stability

Timepoint

Immediately after placing the mini-screw and on days 7, 14, and 30 after placement

Method of measurement

Osstell ISQ RFA device

Secondary outcomes

1

Description

Concentration of inflammatory factors (TNF-α and IL-1β)

Timepoint

Immediately after mini-screw placement and on days 7, 14, and 30

Method of measurement

ELISA Kit

2

Description

Gingival index score

Timepoint

Immediately after placing the mini-screw and on days 7, 14, and 30 after placement

Method of measurement

Modified Gingival Index based on Löe & Silness

3

Description

Pain

Timepoint

Immediately after placing the mini-screw and on 7th after placement

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group 1 (Photodynamic therapy): Titanium miniscrew, 1.6 mm diameter and 10 mm length (American Orthodontics, Sheboygan, WI, USA), coated with zinc oxide nanoparticles (ZnO; Pishgaman Nanomavad Iranian, Mashhad, Iran) using electrostatic spray deposition. After placement, LED irradiation at 450±5 nm and 1000–1400 mW/cm² will be applied for 1 min, repeated once more after force loading.

Category

Treatment - Other

2

Description

Intervention group 2 (ZnO): Titanium miniscrew, 1.6 mm diameter and 10 mm length (American Orthodontics, Sheboygan, WI, USA), coated with zinc oxide nanoparticles (ZnO; Pishgaman Nanomavad Iranian, Mashhad, Iran) using electrostatic spray deposition. No LED irradiation will be applied in this group.

Category

Treatment - Other

3

Description

Intervention group 3 (LED): Titanium miniscrew, 1.6 mm diameter and 10 mm length (American Orthodontics, Sheboygan, WI, USA), uncoated. After placement, LED irradiation at 450±5 nm and 1000–1400 mW/cm² will be applied for 1 min, repeated once more after force loading.

Category

Treatment - Other

4

Description

Intervention group 4 (Positive control): Titanium miniscrew, 1.6 mm diameter and 10 mm length (American Orthodontics, Sheboygan, WI, USA), uncoated and non-irradiated. Patients will use 0.2% chlorhexidine mouthwash (Nazhou, Iran), twice daily for 30 seconds according to manufacturer’s instructions.

Category

Treatment - Other

5

Description

Intervention group 5 (Negative control): Titanium miniscrew, 1.6 mm diameter and 10 mm length (American Orthodontics, Sheboygan, WI, USA), uncoated and non-irradiated, without any adjunctive treatment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, Iran University of Medical Sciences

Full name of responsible person

Rashin Bahrami

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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
Iran 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
Iran University of Medical Sciences
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Position
Assistant Professor
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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