Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of using melatonin hormone locally along with xenograft on bone regeneration and improving the quality of soft tissue in the extracted tooth area

Protocol summary

Study aim
Effect of locally applied melatonin combined with xenograft on bone regeneration and improving attached gingiva thickness in the post-extraction dental socket.

Design
This is a Split-Mouth clinical trial on twenty patients. Randomization is performed using Random Blocks with the goal of allocating the treatment method to the two sides of the mouth (Intervention or Control) to prevent the allocation from being predicted by the researcher. Valid software tools (such as Random.org or SPSS) .

Settings and conduct
This study uses a Split-mouth design. The intervention side in patients with extracted teeth receives a xenograft plus topical melatonin, while the control side receives only the xenograft. Biopsies are taken from both sides after two months, prior to implant placement, by a specialist blinded to the intervention. The study is Double-blind: the patient and implant surgeon are unaware of the melatonin application, with only the researcher knowing the details.

Participants/Inclusion and exclusion criteria
Patients aged 18–50 years who are candidates for early implant placement (Early Implants)Inclusion Criteria: Patients aged 18–50 years, candidates for early implant placement , with four-wall intact dental sockets, and in good general health without uncontrolled systemic diseases such as diabetes and etc.Exclusion Criteria: Patients with a history of allergy to melatonin or xenograft, chronic smokers (>10 cigarettes/day) or alcohol and pregnant or lactating women were excluded to prevent adverse effects and avoid confounding factors affecting bone regeneration.

Intervention groups
In the intervention group, following tooth extraction, the extraction socket is filled with xenograft bone powder combined with melatonin.

Main outcome variables
Effect of topical melatonin combined with xenograft on alveolar bone regeneration and attached gingiva thickness following tooth extraction.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251201068171N1**
Registration date: **2026-01-30, 1404/11/10**
Registration timing: **registered_while_recruiting**

Last update: **2026-01-30, 1404/11/10**
Update count: **0**

Registration date
2026-01-30, 1404/11/10

Registrant information

Name
Mahdi Nozhati Maleki

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
2026-01-20, 1404/10/30

Expected recruitment end date
2026-03-11, 1404/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of using melatonin hormone locally along with xenograft on bone regeneration and improving the quality of soft tissue in the extracted tooth area

Public title

The effect of topical melatonin combined with xenogeneic bone graft powder on bone formation and the width of keratinized gingiva in the extraction site.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with non-restorable teeth who are candidates for implant treatment

Exclusion criteria:

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **20**

More than 1 sample in each individual

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

Bone specimens derived from xenograft alone and from xenograft with melatonin

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: In this split-mouth study, each patient served as their own control. Sites within the mouth (e.g., right or left side) were randomly assigned to the intervention or control. Random allocation was performed using a random number table to minimize bias.

Blinding (investigator's opinion)

Double blinded

Blinding description

1 Patient Blinding • Patients were unaware of which side of the mouth was assigned to the intervention group (melatonin + xenograft) and which side was assigned to the control group (xenograft only) 2 Surgeon and Evaluator Blinding • The surgeon was unaware of the allocation during the intervention and tissue sampling • Clinical and histological evaluators were also blinded to the allocation of each site 3 Allocation Control • Group allocation was performed by an independent person and the information was kept in sealed envelopes • The envelopes were opened only at the time of the intervention by the responsible operator

Placebo

Not used

Assignment

Crossover

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

Golestan Boys' Dormitory, Sari Zamin, First Uphill of Mirdamad, University Square, Tabriz, East Azerbaijan

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East Azarbaijan

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5165995131

Approval date

2025-11-22, 1404/09/01

Ethics committee reference number

IR.TBZMED.REC.1404.622

Health conditions studied

1

Description of health condition studied

Dental socket preservation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Primary Outcome Variable Description:The primary outcome variable is the amount of newly formed bone in the dental socket after using melatonin combined with xenograft compared to xenograft alone.

Timepoint

Time Points of Measurement: 1. Baseline (before tooth extraction / intervention): Measurement of attached gingiva thickness as a reference for soft tissue evaluation 2. Immediately after material placement in the dental socket: Initial clinical observations recorded 3. Week 1 and Week 2 post-surgery: Clinical follow-up including suture closure, swelling, infection, and unpleasant odor 4. Two months post-surgery: • Bone sampling from both intervention and control sites before implant placement • Radiographic assessment to

evaluate bone status and structural changes

Method of measurement

The bone formation is measured using histological analysis (histomorphometry) or image analysis software (Image-Pro Plus) • Results are reported as the percentage of new bone relative to the total tissue section area

2

Description

The secondary outcome variable is attached gingiva thickness around the dental socket, reflecting soft tissue changes after using melatonin combined with xenograft compared to xenograft alone.

Timepoint

1. Baseline (before tooth extraction / intervention): Measurement of attached gingiva thickness using a periodontal probe 2. Immediately after material placement in the dental socket: Recording initial clinical observations of the gingiva 3. Week 1 and Week 2 post-surgery: Clinical assessment of the gingiva, including swelling, inflammation, and soft tissue healing 4. Two months post-surgery: Re-measurement of attached gingiva thickness to evaluate soft tissue changes

Method of measurement

Measurements are performed using a periodontal probe and recorded at predefined time points.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, following tooth extraction, the extraction socket is filled with xenograft bone powder combined with melatonin.This study is designed as a split-mouth trial, in which one side of each patient’s mouth is randomly assigned to receive the intervention (xenograft with melatonin), while the contralateral side serves as the control group and receives xenograft bone powder alone without melatonin.

Category

Treatment - Drugs

2

Description

Control group: In the control group, following tooth extraction, the extraction socket is filled with xenograft bone powder without melatonin.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences, Faculty of Dentistry

Full name of responsible person

Mahdi Nozhati Maleki

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

معاون تحقیقات و فناوری

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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
Mahdi Nozhati Maleki
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
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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
The data will be published as part of a peer-reviewed article
When the data will become available and for how long
Access to the data will be available after final publication of the article.
To whom data/document is available
The data may be accessible by the general public
Under which criteria data/document could be used
provided that proper citation to the published article is made.
From where data/document is obtainable
Requests for access to the data should be directed to the corresponding author via email.
What processes are involved for a request to access data/document
Correspondence via email with the corresponding author.

Comments