Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Sep 2026

Investigation Into The Effect of Vitamin B-Complex on Pain Relief And Healing After The Extraction of The Lower Third Molars

Protocol summary

Study aim

This study evaluates Vitamin B-Complex effectiveness on pain and healing after mandibular third molar surgery, comparing active treatment with placebo using a split-mouth design where each patient serves as their own control.

Design

Single-center, randomized, double-blind, placebo-controlled, split-mouth clinical trial with 17 participants (34 sites) using block randomization with allocation concealment.

Settings and conduct

Single-center trial at a dental school's Oral Surgery Department using a split-mouth design. Double-blinding was maintained with identical Vitamin B-Complex and placebo packaging. Participants, investigators, and outcome assessors were all blinded to treatment assignments throughout the study.

Participants/Inclusion and exclusion criteria

inclusion: Healthy individuals (ASA I status) aged 18 to 35 years requiring surgical extraction of both impacted or semi-impacted mandibular third molars. exclusion: Use of non-steroidal anti-inflammatory drugs within one week prior to surgery; tobacco, alcohol, or illicit drug use; pre-existing infection at third molar sites; known allergy to B vitamin compounds; presence of systemic diseases.

Intervention groups

This split-mouth study administers both Vitamin B-Complex and placebo to each participant, with two tablets daily for one week, alongside standardized ibuprofen for pain, to isolate the vitamin's effect while maintaining consistent pain management.

Main outcome variables

Pain Intensity: Measured using Visual Analogue Scale (VAS) at 1, 6, 12, 24, 48, and 72 hours postoperatively. Wound Healing: Assessed clinically at 2 and 3 weeks post-surgery using three-stage healing scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251104067878N1**
Registration date: **2025-11-07, 1404/08/16**
Registration timing: **prospective**

Last update: **2025-11-07, 1404/08/16**
Update count: **0**

Registration date

2025-11-07, 1404/08/16

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-16, 1404/08/25

Expected recruitment end date

2025-12-01, 1404/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation Into The Effect of Vitamin B-Complex on Pain Relief And Healing After The Extraction of The Lower Third Molars

Public title

Vitamin B-Complex Effect on Pain of Extraction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age: Between 18 and 35 years old. Health Status: Classified as ASA I (A normal healthy patient). Dental Condition: Required surgical removal of both left and right impacted or semi-impacted mandibular third molars (lower wisdom teeth).

Exclusion criteria:

Medication Use: Had used any non-steroidal anti-inflammatory drugs (NSAIDs) or analgesics in the one week prior to surgery. Substance Use: Were consumers of tobacco, alcohol, or illicit drugs. Pre-existing Infection: Had signs or symptoms of infection related to the third molar in the week before surgery. Allergy: Had a known allergy to compounds in the Vitamin B family. Systemic Diseases: Had any specific systemic diseases (this was asked in the patient information form to screen for ineligible conditions).

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **17**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization process in this study was structured as follows: Method of Randomization: Block Randomization was used. This method ensures a balanced assignment of interventions (e.g., control and intervention) throughout the enrollment period, preventing a situation where one group has significantly more participants than the other at any point. Unit of Randomization: The unit was the surgical site (tooth) within each participant. This is a "split-mouth" design where each patient served as their own control, with one side randomly assigned to the intervention and the other to the control. Randomization Strata: The thesis does not mention the use of stratified randomization. Therefore, no specific patient characteristics (such as age or gender) were used as strata to create balanced groups. Tools Used: The random sequence was generated using computer software (specifically, SPSS or other random allocation software). How the Random Sequence was Built: An independent person (not involved in patient recruitment or outcome assessment) used the computer software to generate a pre-determined, unpredictable random allocation sequence. This sequence dictated which surgical site (left or right) would receive the Vitamin B-Complex and which would receive the placebo for each participant. Allocation Concealment: Yes, allocation concealment was carried out. The intervention and placebo were prepared in identical, coded bottles or containers according to the random sequence. This ensured that the surgeons and investigators enrolling participants could not foresee the upcoming assignment, thus preventing selection bias.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this randomized controlled trial, blinding was implemented for key groups to minimize bias, achieved through the following methods: Participants: Participants were blinded. Both the active drug (Vitamin B-Complex) and the control (placebo) were prepared in identical, indistinguishable capsules. This ensured that participants did not know whether they were receiving the intervention or the placebo for each specific surgical site. Investigators / Healthcare Providers: The principal investigator and healthcare providers involved in administering the interventions were blinded. The randomization codes were pre-generated, and the interventions were packaged and labeled according to these codes. The individuals dispensing the medication capsules had no knowledge of which bottle contained the active drug versus the placebo. Outcome Assessors: The outcome assessors were explicitly blinded. The individual(s) responsible for collecting post-operative data, including pain scores (VAS) and healing assessments, had no information about the group assignment (intervention or control) for each surgical site. Data Collectors: The data collectors, who were responsible for recording the outcomes from the assessments, were the same as the blinded outcome assessors, thus maintaining the blinding throughout this stage. The following groups were not blinded or their blinding status was not specified: Data Analysts: The blinding of the data analyst was not mentioned in the thesis manuscript. Data and Safety Monitoring Board (DSMB): The study did not report the establishment of a DSMB. The blinding was maintained until the data collection for all primary and secondary outcomes was complete

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Dentistry Faculty - Islamic Azad University of Medical Sciences, Tehran
Street address
No. 9, 9th Neistan, Pasdaran Street
City
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Province
Tehran
Postal code
1946853314
Approval date
2023-05-14, 1402/02/24
Ethics committee reference number
IR.IAU.DENTAL.REC.1402.018

Health conditions studied

1

Description of health condition studied
Postoperative sequelae following surgical extraction of impacted or semi-impacted mandibular third molars, specifically focusing on pain management and wound healing complications. The condition involves common postoperative symptoms including acute pain, inflammation, and delayed soft tissue recovery after mandibular third molar surgery. This study examines therapeutic interventions to improve recovery outcomes following this common oral surgical procedure.
ICD-10 code
M27.2
ICD-10 code description
Inflammatory conditions of jaws

Primary outcomes

1

Description
Postoperative Pain Intensity: Measured using the Visual Analogue Scale (VAS), a 0-10 point scale where 0 represents "no pain" and 10 represents "the worst pain imaginable." Measurements are recorded at 1, 6, 12, 24, 48, and 72 hours after the surgical procedure. Wound Healing Status: Assessed clinically using a three-stage healing scale: 1) No healing (open wound with exposed bone), 2) Minimal healing with mucosal erythema, and 3) Healed with normal mucosa. Evaluations are performed at 2 weeks and 3 weeks post-surgery.
Timepoint
Pain Intensity: Measured at 1, 6, 12, 24, 48, and 72 hours after the surgical intervention. Wound Healing Status: Assessed at 2 weeks and 3 weeks after the surgical intervention.
Method of measurement
Pain Intensity: Measured using a standardized Visual Analogue Scale (VAS), a 10-cm horizontal line where the left end (0) represents "no pain" and the right end (10) represents "the worst pain imaginable." Patients self-report their pain level by marking a point on the line.Wound Healing Status: Assessed through direct clinical examination by a trained evaluator using a predefined three-stage healing scale based on visual inspection of the surgical site

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Oral Vitamin B-Complex tablets (2 tablets daily for one week) plus Ibuprofen as needed for pain management.
Category
Treatment - Drugs

2

Description
Control group: Identical placebo tablets (2 tablets daily for one week) plus Ibuprofen as needed for pain management.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Islamic Azad University, Tehran Medical Branch, Dental School
Full name of responsible person
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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?
Yes
Title of funding source
Islamic Azad University
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
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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