

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of vitamin B complement administration on pain and sensory problems following implant surgery in the posterior portion of mandible

Protocol summary

Study aim

Investigating the effect of vitamin B complement administration on pain and sensory problems following implant surgery in the posterior portion of mandible

Design

Clinical trial with parallel intervention group, without blinding, randomized, random sampling method. Randomization method is simple and with a random number table. 46 people will be selected (23 people will receive routine treatment after implantation and 23 people will receive vitamin B complex pills daily for two weeks in addition to routine treatment.

Settings and conduct

The study will be performed in the Periodontics department of Tabriz Dental School. 23 people are prescribed vitamin B complex pills for two weeks (intervention group) in addition to routine treatment, and 23 people are prescribed only routine treatment (control group). The patient is aware of his pills. The incidence of sensory symptoms will be measured.

Participants/Inclusion and exclusion criteria

Entry requirements: Satisfaction to participate in the study, Sensory disorder and unilateral pain in the mandible because of the implant placement, Healthy patients without the use of special drugs. Exit conditions: Previous history of inferior alveolar nerve injury, Inability of the patient to follow the treatment and clinical examinations of the study, Patients with clinical and radiographic symptoms indicating nerve damage due to implant or instrument invasion of the nerve canal .

Intervention groups

46 patients will be divided into two groups. In addition to routine treatment, the intervention group will receive one vitamin B tablet daily for two weeks, and the control group will receive only routine post-implant treatment.

Main outcome variables

Pain and numbness after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180630040290N5**

Registration date: **2020-09-03, 1399/06/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-03, 1399/06/13**

Update count: **0**

Registration date

2020-09-03, 1399/06/13

Registrant information

Name

Amir Reza Babaloo

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 44 3428 3025

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-09-10, 1399/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of vitamin B complement administration on pain and sensory problems following implant surgery in the posterior portion of mandible

Public title

Evaluation of the effect of vitamin B supplementation on pain caused by implant surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction to participate in the study Sensory disorder and unilateral pain in the mandible due to the implant placement Healthy patients without the use of special drugs

Exclusion criteria:

Inability of the patient to follow the treatment and clinical examinations of the study Previous history of inferior alveolar nerve injury People with primary neurological problems such as neuropathies and paresthesia

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method is randomly available among individuals referring to periodontics department of Tabriz dental faculty. The randomization method is simple and the unit is individual, our tool for randomization is the randomized number chart. Furthermore, the allocation of treatment to patients is done randomly. To do this, the types of the treatment are identified with code A (prescribing vitamin B) and B (not prescribing vitamin B) and then the treatment are sealed in envelopes that will be placed in a box and stirred. Then they are randomly chosen from the box and after observing the code, the treatment is given to the patient.

Blinding (investigator's opinion)

Not blinded

Blinding description

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

Central office of Tabriz University of Medical Sciences, Golgasht Ave, Azadi Blvd

City

Tabriz

Province

East Azarbaijan

Postal code

5165687386

Approval date

2020-08-24, 1399/06/03

Ethics committee reference number

IR.TBZMED.REC.1399.551

Health conditions studied

1

Description of health condition studied

Mandibular implants

ICD-10 code

Z96.5

ICD-10 code description

Presence of tooth-root and mandibular implants

Primary outcomes

1

Description

Pain after surgery

Timepoint

It will be done 14, 28 days and 1, 2 and 3 months after receiving treatment.

Method of measurement

Visual Analogue Scale

2

Description

Postoperative malaise

Timepoint

It will be done 14, 28 days and 1, 2 and 3 months after receiving treatment.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to routine treatment, the intervention group will receive vitamin B complex -50 milligram tablets daily for two weeks , immediately after implantation.

Category

Treatment - Other

2

Description

Control group: Patients in the control group will receive routine post-implant treatment .

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences Dentistry
Faculty Periodontics Department

Full name of responsible person

Amirreza Babaloo

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Dentistry Faculty of Tabriz, Golgasht Ave, 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

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Web page address

<https://researchvice.tbzmed.ac.ir>

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Amir reza Babaloo

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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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