

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of vitamin D3 versus not receiving vitamin D3 on the inflammation and complications after hidden third molar surgery in mandible in patients with vitamin D3 deficiency: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of vitamin D3 versus not receiving vitamin D3 on the inflammation and complications after hidden third molar surgery in the mandible

Design

This is a randomized clinical trial, phase II, in which 30 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with vitamin D3 deficiency who are the candidate for hidden third molar surgery in the mandible and will refer to School of Dentistry during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 40 years; Candidate for third molar surgery in mandible; Vitamin D3 deficiency
Exclusion criteria: Narcotic addiction; Cigarette smoking; Diabetes; Renal failure; Bowel inflammatory disease

Intervention groups

Intervention group 1: Hidden third molar surgery in mandible in one side by random without receiving vitamin D3
Intervention group 2: Hidden third molar surgery in mandible in the other side 10 days after the first surgery plus tablet vitamin D 0.25 mg once daily for 3 months and ampulla vitamin D 300,000 IU once a month for 3 months

Main outcome variables

Primary outcome: Cheek inflammation
Mouth opening
Pain on surgery location

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N227**
Registration date: **2018-07-25, 1397/05/03**

Registration timing: **retrospective**

Last update: **2018-07-25, 1397/05/03**

Update count: **0**

Registration date

2018-07-25, 1397/05/03

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-01, 1396/12/10

Expected recruitment end date

2018-06-18, 1397/03/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D3 versus not receiving vitamin D3 on the inflammation and complications after hidden third molar surgery in mandible in patients with vitamin D3

deficiency: a randomized clinical trial

Public title

Effect of vitamin D3 versus not receiving vitamin D3 on the inflammation and complications after hidden third molar surgery in mandible in patients with vitamin D3 deficiency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 40 years; Candidate for third molar surgery in mandible; Vitamin D3 deficiency

Exclusion criteria:

Narcotic addiction; Cigarette smoking; Diabetes; Renal failure; Bowel inflammatory disease

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Choosing the third molar of the mandible in either side of the patient by throwing the coin

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-02-24, 1396/12/05

Ethics committee reference number

IR.UMSHA.REC.1396.818

Health conditions studied

1

Description of health condition studied

Vitamin D deficiency

ICD-10 code

E50

ICD-10 code description

Vitamin D deficiency

Primary outcomes

1

Description

Cheek inflammation

Timepoint

1, 3, 7, and 10 days after surgery

Method of measurement

By physical examination

2

Description

Mouth opening

Timepoint

1, 3, 7, and 10 days after surgery

Method of measurement

By physical examination

3

Description

Pain on surgery location

Timepoint

1, 3, 7, and 10 days after surgery

Method of measurement

By visual analog scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Third molar surgery in mandible in one side by random without receiving vitamin D3

Category

Treatment - Surgery

2

Description

Intervention group 2: Third molar surgery in mandible in the other side 10 days after the first surgery plus tablet vitamin D 0.25 mg once daily for 3 months and ampulla vitamin D 300,000 IU once a month for 3 months

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry

Full name of responsible person

Golnaz Ziaee

Street address

School of Dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

goli0311@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Golnaz Ziaee

Position

Dental Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

School of Dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

goli0311@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Amir Hosein Babaei Soroor

Position

Oral, Maxillofacial Surgeon

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

School of Dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

dr.amirsoroor@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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