Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Babaee 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