

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the Effect of Preoperative Vitamin D on Postoperative Ionized Calcium Levels in Patients Undergoing Total Thyroidectomy

#### Protocol summary

##### Study aim

Investigate the effect of vitamin D injection before surgery on ionized calcium level and prevention of postoperative hypocalcemia in patients undergoing thyroid surgery.

##### Design

This study is a randomized, double-blind, parallel-group, controlled clinical trial conducted on 68 patients who are candidates for total thyroidectomy. Eligible patients will be randomly allocated into two groups: intervention (n = 34) and control (n = 34). Randomization will be performed through drawing method.

##### Settings and conduct

Study setting: surgery ward of Shahid Jalil Hospital in the city of Yasuj; Study population: Patients with thyroid diseases who will be candidates for total thyroidectomy surgery; Type of blinding: Double-blind; Method of blinding: In this study, both the patients and the outcome assessors will not be aware of the allocation of participants to the intervention and control groups, and the group allocation process will be performed randomly.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 70 years; Candidates requiring total thyroidectomy Exclusion criteria: Diagnosis of diabetes mellitus; Use of systemic corticosteroids for more than 7 days within the past three months; Presence of any underlying disease affecting parathyroid hormone, vitamin D, calcium, or albumin levels (e.g., chronic kidney disease); History of a major previous surgical procedure, such as total laryngectomy or parathyroidectomy; Preoperative hypocalcemia; Diagnosis of parathyroid adenoma.

##### Intervention groups

Intervention group (n=34): single intramuscular vitamin D injection (15 mcg / 600 IU) two weeks before surgery. Control group (n=34): no vitamin D injection.

##### Main outcome variables

Ionized calcium level ; Vitamin D level

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20251118068041N1**

Registration date: **2026-02-16, 1404/11/27**

Registration timing: **prospective**

Last update: **2026-02-16, 1404/11/27**

Update count: **0**

##### Registration date

2026-02-16, 1404/11/27

##### Registrant information

##### Name

Maryam Jamshidi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3322 4721

##### Email address

maryam.jamshidi2004@gmail.com

##### Recruitment status

**recruiting**

##### Funding source

##### Expected recruitment start date

2026-02-20, 1404/12/01

##### Expected recruitment end date

2027-02-20, 1405/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the Effect of Preoperative Vitamin D on Postoperative Ionized Calcium Levels in Patients Undergoing Total Thyroidectomy

#### Public title

Effect of vitamin D in Thyroidectomy

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age between 18 and 70 years Candidates requiring total thyroidectomy

##### Exclusion criteria:

Diagnosis of diabetes mellitus Use of systemic corticosteroids for more than 7 days within the past three months Pregnancy History of ischemic heart disease Presence of any underlying disease affecting parathyroid hormone, vitamin D, calcium, or albumin levels (e.g., chronic kidney disease) History of a major previous surgical procedure, such as total laryngectomy or parathyroidectomy Substance abuse / drug addiction Preoperative hypocalcemia Change in the type of surgical procedure Patients with intraoperative parathyroid injury, including cases where the surgeon reports injury, autotransplantation of parathyroid tissue, or evidence of parathyroid ischemia Diagnosis of parathyroid adenoma before, during, or after surgery

#### Age

From **18 years** old to **70 years** old

#### Gender

Both

#### Phase

0

#### Groups that have been masked

- Participant
- Investigator

#### Sample size

Target sample size: **68**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Each participant will be assigned a unique number. Then, by simple random draw, participants will be allocated to each group using simple random sampling, with the total sample equally divided into the control group (n=34) and the intervention group (n=34).

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Type of blinding: Double-blind; Method of blinding: In this study, both patients and outcome assessors will be unaware of the intervention received by each participant; to maintain blinding, the vitamin D injections in the intervention group and no injection in the control group will be managed so that outcome assessors will not be aware of the differences, and the appearance of the injection process will be kept similar for both groups.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics Committee of Yasuj University of Medical Sciences

###### Street address

Shahid Motahari Blvd., Yasuj

###### City

Yasuj

###### Province

Kohgiluyeh-va-Boyerahmad

###### Postal code

75918-74831

##### Approval date

2024-05-08, 1403/02/19

##### Ethics committee reference number

IR.YUMS.REC.1403.021

### Health conditions studied

#### 1

##### Description of health condition studied

Patients with thyroid disorders who are candidates for total thyroidectomy

##### ICD-10 code

E83.51

##### ICD-10 code description

Hypocalcemia

### Primary outcomes

#### 1

##### Description

Ionized calcium level after surgery

##### Timepoint

Every 12 hours for 2 days postoperatively (4 measurements)

##### Method of measurement

Ionized calcium will be measured using standard laboratory biochemical assays.

### Secondary outcomes

#### 1

##### Description

Hypocalcemia-related complications

##### Timepoint

Continuously monitored for 2 days postoperatively

##### Method of measurement

Assessed by clinical evaluation and patient monitoring

+98 74 3333 7001

**Email**

maryam.jamshidi2004@gmail.com

**2**

**Description**

Requirement for additional calcium supplementation

**Timepoint**

During the 2-day postoperative period

**Method of measurement**

Recorded from patient treatment logs

**3**

**Description**

Vitamin D levels

**Timepoint**

Measured at baseline and before surgery

**Method of measurement**

Measured using standard laboratory biochemical assays

**Intervention groups**

**1**

**Description**

Intervention group: In this group, patients will receive a single intramuscular injection of vitamin D3 at a dose of 15 micrograms (600 IU), purchased from Darou Pakhsh Pharmaceutical Company, two weeks before undergoing total thyroidectomy. Each patient will receive one injection.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: In this group, patients will not receive any injection two weeks before surgery and will receive routine hospital care. No additional drugs or supplementary interventions will be provided.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Jalil Hospital

**Full name of responsible person**

Maryam Jamshidi

**Street address**

Gharani Blvd, Yasuj

**City**

Yasuj

**Province**

Kohgiluyeh-va-Boyerahmad

**Postal code**

759113615

**Phone**

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Yasuj University of Medical Sciences

**Full name of responsible person**

Dr. Sirus Salehi-Nassab

**Street address**

Qorani Blvd, Yasuj

**City**

Yasuj

**Province**

Kohgiluyeh-va-Boyerahmad

**Postal code**

759113615

**Phone**

+98 21 8670 5503

**Email**

shahidjalil@yums.ac.ir

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Yasuj 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**

Yasuj University of Medical Sciences

**Full name of responsible person**

Mohammad Bagher Jahantab

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

**Street address**

Gharani Blvd.

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

759113615

**Phone**

+98 74 3334 6079

**Email**

parsim90@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Mohamad Bagher Jahantab

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

**Street address**

Qorani Blvd, Yasuj

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

759113615

**Phone**

+98 21 8670 5503

**Email**

parsim90@mail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Mohamad Bagher Jahantab

**Position**

Mohamad Bagher Jahantab

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

**Street address**

Qorani Blvd., Yasuj

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

759113615

**Phone**

+98 21 8670 5503

**Email**

parsim90@mail.com

## 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**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable