

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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)

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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		Other design features	
Public title	Effect of vitamin D in Thyroidectomy	Secondary Ids	empty
Purpose	Treatment	Ethics committees	
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 procedurePatients 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	<u>1</u>	
Age	From 18 years old to 70 years old	Ethics committee	
Gender	Both	Name of ethics committee	Ethics Committee of Yasuj University of Medical Sciences
Phase	0	Street address	Shahid Motahari Blvd., Yasuj
Groups that have been masked	- Participant - Investigator	City	Yasuj
Sample size	Target sample size: 68	Province	Kohgiluyeh-va-Boyer-Ahmad
Randomization (investigator's opinion)	Randomized	Postal code	75918-74831
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).	Approval date	2024-05-08, 1403/02/19
Blinding (investigator's opinion)	Double blinded	Ethics committee reference number	IR.YUMS.REC.1403.021
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.	Health conditions studied	
Placebo	Not used	<u>1</u>	
Assignment	Parallel	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	
		<u>1</u>	
		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	
		<u>1</u>	
		Description	Hypocalcemia-related complications
		Timepoint	Continuously monitored for 2 days postoperatively
		Method of measurement	

Assessed by clinical evaluation and patient monitoring

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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-Boyer-Ahmad

Postal code

759113615

Phone

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Dr. Sirus Salehi-Nassab

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Grant name

Grant code / Reference number

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

No

Title of funding source

Yasouj 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

Yasouj 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

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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

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