

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of preoperative vitamin D supplementation on postoperative hypocalcemia in patients with vitamin D deficiency candidate for total thyroidectomy

#### Protocol summary

##### Summary

In current study, we aim to evaluate effect of preoperative vitamin D supplements administration effect in prevention of postoperative hypocalcemia in thyroidectomy patients with moderate and severe vitamin D deficiency. Of all patients with thyroidectomy indication referring to thoracic surgery clinic, during first visit, with due attention to serum vitamin D test results, 100 patients will enroll study and divide to case and control groups randomly. Afterward, case group patients will receive 50000 IU vitamin D supplement weekly up to 4 weeks, and control group patients will receive placebo in the same prescription. All patients will undergo thyroidectomy at the end of the 4th week. Subsequent to surgery, in order to evaluate postoperative hypocalcemia, serum total and ionized calcium levels will be checked in three period as follows: 6 to 12 hours after surgery, 18 to 24 hours after surgery and 48 to 72 hours after surgery. In addition, serum calcium levels will be checked at the end of the 2nd week postoperative to assess the long term hypocalcemia incidence in these patients.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016062016077N6**

Registration date: **2016-06-29, 1395/04/09**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-06-29, 1395/04/09

##### Registrant information

##### Name

Ali Ramouz

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3441 3895

##### Email address

ali.ramouz@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2015-08-23, 1394/06/01

##### Expected recruitment end date

2016-07-22, 1395/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of preoperative vitamin D supplementation on postoperative hypocalcemia in patients with vitamin D deficiency candidate for total thyroidectomy

##### Public title

Effect of vitamin D in prevention of postoperative hypocalcemia in total thyroidectomy patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: multi nodular goiter; thyroid cancers; patients candidates fo thyroidectomy who suffer

moderate to severe vitamin D deficiency in preoperative tests. Exclusion criteria: previous history of head and neck surgeries; coexisting parathyroid diseases; suffering diseases that affect calcium and vitamin D metabolism; patients who have injured or dissected parathyroid glands during surgery; patients who received vitamin supplements before surgery.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

Sealed envelope method

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of the research and technology department, Tabriz University of Medical sciences

**Street address**

Research department- laneshgah street- Tabriz

**City**

Tabriz

**Postal code****Approval date**

2016-06-18, 1395/03/29

**Ethics committee reference number**

ir.tbzmed.rec.1395.214

**Health conditions studied****1****Description of health condition studied**

Postoperative hypocalcemia

**ICD-10 code**

E 89.0

**ICD-10 code description**

Postprocedural endocrine and metabolic disorders, not elsewhere classified

**Primary outcomes****1****Description**

Serum calcium level

**Timepoint**

Before surgery, 6 to 12 hours after surgery, 18 to 24 hours after surgery and 48 to 72 hours after surgery

**Method of measurement**

According to laboratory tests

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Vitamin D 50000 IU weekly for 4 week administration in intervention group

**Category**

Treatment - Drugs

**2****Description**

Placebo administration instead of vitamin D in control group

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Taleghani hospital

**Full name of responsible person**

Seyed Ziaeddin Rasihashemi

**Street address****City**

Tabriz

**2****Recruitment center****Name of recruitment center**

Emma Reza hospital

**Full name of responsible person**

Seyed Ziaeddin Rasihashemi

**Street address****City**

Tabriz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ali Ramouz

**Street address**

Imam Reza hospital, Daneshgah street

**City**

Tabriz

**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**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ali Ramouz

**Position**

medical student

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Dr. Seyed Ziaeddin Rasihashemi

**Position**

Assistant professor

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## Person responsible for updating data

### Contact

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Ali Ramouz

**Position**

Medical Student

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*