Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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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- Ianeshgah 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
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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