Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Evaluation of the prophylactic effects of oral calcium supplement alone and with calcitriol in the development of symptomatic hypocalcemia after total or near-total thyroidectomy

Protocol summary

Study aim
Evaluation the prophylactic effects of oral calcium supplement alone and with calcitriol in the development of symptomatic hypocalcemia after total or near-total thyroidectomy

Design
Clinical trial with control group, with factorial group, Single blind, randomized, phase 3 on about 100 patients, RandList1.2 software was used for randomization.

Settings and conduct
The study on patients who are candidates for total or near-total thyroidectomy will be performed in Imam Reza and Sina Hospital in Tabriz. It is Single blind and the participants are blinded.

Participants/Inclusion and exclusion criteria
All patients will be included in the study after completing the study in terms of compliance with inclusion and exclusion criteria and with knowledge of the objectives and method of the study and certainty in terms of confidentiality of information and the optionality of cooperation after completing the informed consent form.

Intervention groups
The patients included in the study (about 100 people) will first be randomly divided into three group, In one group, calcium will be given only if hypocalcemia occurs. In the other group, only calcium carbonate tablets will be given, and in the third group, calcium carbonate tablets will be given with calcitriol capsules.

Main outcome variables
Serum calcium levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210513051285N1**
Registration date: **2022-02-24, 1400/12/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-24, 1400/12/05**
Update count: **0**

Registration date
2022-02-24, 1400/12/05

Registrant information

Name
Amir Alizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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amir313.alizadeh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-08, 1399/11/20

Expected recruitment end date
2022-03-01, 1400/12/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the prophylactic effects of oral calcium supplement alone and with calcitriol in the development of symptomatic hypocalcemia after total or near-total thyroidectomy

Public title
Evaluation of the effects of calcium supplementation alone and with calcitriol in preventing the symptoms of hypocalcemia following total or near total thyroidectomy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
In this study, patients who are candidates for surgery and removal of both thyroid lobes total or near-total due to multinodular goiter or thyroid cancer will be selected.
Exclusion criteria:
Patients with preoperative hypocalcemia Patients with intraoperative parathyroid injury (mentioned by the surgeon , autograft and ischemic symptoms), Presence of parathyroid adenoma before or after surgery or any underlying disease that impairs parathyroid hormone, vitamin D, calcium, and albumin levels (such as chronic kidney disease or known diseases of malabsorption and indigestion) , Patients who have undergone extensive cervical lymphadenectomy during thyroidectomy, Patients with hypercalcemia and hypercalciuria, patients with calcium kidney stones, ventricular fibrillation, digoxin toxicity, sarcoidosis and Vit D poisoning. Patient dissatisfaction with participating in this study The presence of a previous major procedure (such as total laryngectomy and parathyroidectomy), receiving prophylactic medication for osteoporosis (including calcium and vitamin D supplementation).
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of people to be in one of the three groups will be done using RandList1.2 software and as a blind.
Blinding (investigator's opinion)
Single blinded
Blinding description
All patients will be informed of the objectives and method of the study and will be partially informed about the confidentiality of information and the optionality of cooperation after completing the informed consent form . The patients included in the study (about 100 people) will first be randomly divided into three groups and each group will receive a different intervention but they will not know in which group they will be placed.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
1166614766
Approval date
2021-02-08, 1399/11/20
Ethics committee reference number
IR.TBZMED.REC.1399.1062

Health conditions studied

1

Description of health condition studied
Symptomatic hypocalcemia after total or near-total thyroidectomy
ICD-10 code
E89
ICD-10 code description
Postprocedural endocrine and metabolic complications and 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, 48 to 72 hours after surgery, next in case of recurrence of hypocalcemia and discharge time
Method of measurement
Based on laboratory tests

Secondary outcomes

1

Description
Clinical signs of calcium deficiency
Timepoint
Every 2 hours
Method of measurement
History and examination

Intervention groups

1

Description
Control group: Calcium will only be given if hypocalcemia occurs
Category
N/A

2

Description
Intervention group: About 12 hours after surgery, when the patient is able to tolerate orally, calcium carbonate 500 mg tablets will be started and continued every 8 hours regardless of the presence or absence of hypocalcemia symptoms.
Category
Prevention

3

Description
Intervention group: About 12 hours after surgery when the patient is able to tolerate orally, calcium carbonate 500 mg tablets and oral calcitriol0.25 µg capsules will be started regardless of the presence or absence of hypocalcemia symptoms, then calcium carbonate tablets every 8 hours and calcitriol capsules daily will be prescribed.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Fariborz Rousta
Street address
Imam Reza Hospital
City
Tabriz
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East Azarbaijan
Postal code
5166614756
Phone
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2

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
fariborz Rousta
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology, Tabriz University of Medical Sciences
Full name of responsible person
Dr.Parviz Shahabi
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parvizshahabi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Amir Alizadeh

Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

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Assistant professor
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Subspecialist
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Person responsible for updating data

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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The data will be available without mentioning the name of the participant and in encrypted form
When the data will become available and for how long
6 months after printing the results
To whom data/document is available
Vice Chancellor for Research, Journals, People Approved by the Vice Chancellor for Research
Under which criteria data/document could be used
After sending the request and mentioning the reason for the request, it can be used if all members of the research agree
From where data/document is obtainable
Amir Alizadeh Email: amir313.alizadeh@gmail.com
What processes are involved for a request to access data/document
After sending the request to the above email, the data will be available if all research members agree
Comments