

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)

Phone

+98 44 3523 2940

Email address

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 calcitriol 0.25 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

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3337 3920

Email

fariborz_roosta@yahoo.com

2

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

fariborz Rousta

Street address

Sina Hospital

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Tabriz

Province

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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

Street address

Daneshgah street, Imam Reza Hospital

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Tabriz

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Postal code

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Phone

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Email

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Medical student

Latest degree

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Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Fariborz Rosta

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Thoracic Surgery

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Person responsible for updating data

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Amir Alizadeh

Position

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