Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative Evaluation of the Impact of Routine Calcium intake versus Recommended Calcium Intake in Patients Undergoing Total Thyroidectomy

Protocol summary

Study aim

Comparative determination of the effect of routine calcium treatment regimen and the recommended calcium intake regimen in patients undergoing total thyroidectomy

Design

it is a randomized clinical trial study with a control group in a single-blind manner on 40 patients in 2 groups.

Settings and conduct

In a period of 12 months, among the patients referred to Sina Hospital in Tehran, who are candidates for total thyroidectomy surgery in 1402-1404, are included in the study. The patients in this study were candidates for surgery and resection of both thyroid lobes due to multinodular goiter or thyroid cancer. After selecting the patients, the serum calcium level of each person will be measured before the operation. Calcium levels of patients will be checked 12 hours before surgery and every 8 hours after surgery, patients will be checked for signs and symptoms of hypocalcemia and serum calcium levels, and the presence and absence of symptoms will be collected in the checklist.

Participants/Inclusion and exclusion criteria

Patients over 18 years of age, potential early diagnosis of thyroid cancer. planned surgery: complete and bilateral thyroidectomy, with or without various lateral neck extensions, absence of preoperative hypercalcemia, or Any type of kidney disorder that causes calcium metabolism disorder, absence of abnormal preoperative parathyroid hormone level or concomitant parathyroid diseases, absence of history of any type of thyroid or neck surgery.

Intervention groups

Patients were randomly divided into two groups of routine treatment diet (500 mg calcium every 8 hours and 1000 units of calcitriol daily) and high dose calcium treatment (500 mg calcium carbonate every 8 hours, 0.5 microgram calcitriol every 12 hours and 500 mg calcifort every 6 hours)

Main outcome variables

Serum calcium level before and after surgery, Symptoms of hypocalcemia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220530055031N5**
Registration date: **2024-06-10, 1403/03/21**
Registration timing: **registered_while_recruiting**

Last update: **2024-06-10, 1403/03/21**
Update count: **0**

Registration date

2024-06-10, 1403/03/21

Registrant information

Name

Seyed Amir Miratashi Yazdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6312 0000

Email address

amiratashi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-30, 1403/03/10

Expected recruitment end date

2024-11-30, 1403/09/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative Evaluation of the Impact of Routine Calcium intake versus Recommended Calcium Intake in Patients Undergoing Total Thyroidectomy

Public title
Investigation of different calcium treatment regimens on patients after thyroidectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Potential early diagnosis of thyroid cancer total thyroidectomy With or without the spread of cancer to the lateral parts of the neck Absence of hypercalcemia before surgery or any kind of kidney disorder that causes calcium metabolism disorder Absence of abnormal preoperative parathyroid hormone levels or concomitant parathyroid diseases No history of any type of thyroid or neck surgery Age over 18 years
Exclusion criteria:
Pathological diagnosis after surgery except papillary thyroid cancer Patients who have a history of taking calcium supplements before surgery History of kidney or urinary tract disease History of radiation therapy or other tumors
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to one of 2 treatment groups by block randomization method. Block randomization with different block sizes is used for random allocation. Block sizes are multiples of 2. Initially, block sizes are randomly selected. Finally, one of the different permutations is determined for the equal group size. Random numbers are done using Excel. The study will be done blindly. In such a way that the patients do not know the type of supplement received and the drugs are given to the patients in the same packaging without specifying the specifications, and only the researcher knows the type of drug prescribed and the doctor and the person in charge of evaluating the patients who talk to the patient, They do not know the prescribed medicine.
Blinding (investigator's opinion)
Double blinded
Blinding description
With the help of getting random numbers using Excel for each patient. The study will be done blindly. In such a way that the patients do not know the type of supplement received and the drugs are given to the patients in the same packaging without any specifications, and only the researcher knows the type of drug prescribed and the doctor and the person in charge of evaluating the patients who talk to the patient about the type of drug Prescribed do not know.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of medical faculty of Tehran University of Medical Sciences
Street address
Room 604, 6th floor, Tehran University of Medical Sciences Central Building, Keshavarz Blvd., Qods St. intersection
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2024-05-15, 1403/02/26
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1403.065

Health conditions studied

1

Description of health condition studied
Hypocalcemia after total thyroidectomy surgery
ICD-10 code
E83.51
ICD-10 code description
Hypocalcemia

Primary outcomes

1

Description
Serum calcium level before surgery
Timepoint
The calcium level of patients will be checked 12 hours before surgery and will be collected in the checklist.
Method of measurement
The patient's serum calcium level, measured in the laboratory

2

Description
Serum calcium level after surgery
Timepoint
The calcium level of the patients will be checked every 8 hours after the operation and will be collected in the checklist.
Method of measurement
The patient's serum calcium level, measured in the laboratory

Secondary outcomes

1

Description
Symptoms caused by hypocalcemia
Timepoint
Every 8 hours after the operation, the patients will be checked for signs and symptoms of hypocalcemia and the presence and absence of symptoms will be collected in the checklist.
Method of measurement
Expert opinion

Intervention groups

1

Description
intervention group: In this group, they will be treated with a high-dose calcium regimen (500 mg calcium carbonate every 8 hours, 0.5 microgram calcitriol 1 tablet every 12 hours, and 500 mg calcifort every 6 hours) after surgery. The calcium level of patients will be checked 12 hours before surgery and 8 hours after surgery, and every 8 hours after surgery, patients will be checked for signs and symptoms of hypocalcemia and serum calcium level. The presence and absence of symptoms are collected in the checklist. Patients are discharged if there are no hypocalcemic symptoms and normocalcemic serum. Patients will return to the clinic for clinical examinations 5 days after the operation, and the serum calcium level of the patients will be checked again.
Category
Treatment - Drugs

2

Description
Control group: A group of patients received only routine treatment (500 mg of calcium every 8 hours and 1000 units of calcitriol daily) after surgery. The calcium level of patients will be checked 12 hours before surgery and 8 hours after surgery, and every 8 hours after surgery, patients will be checked for signs and symptoms of hypocalcemia and serum calcium level. The presence and absence of symptoms are collected in the checklist. Patients are discharged if there are no hypocalcemic symptoms and normocalcemic serum. Patients will return to the clinic for clinical examinations 5 days after the operation, and the serum calcium level of the patients will be checked again.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Seyed Amir Miratashi Yazdi
Street address
Sina Hospital, Imam Khomeini Ave.
City
Tehran
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1136746911
Phone
+98 66 3485 0010
Email
hosp_sina@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Akbar Fotouhi
Street address
Research and Technology Vice-Chancellor, 6th floor, Central Organization of the University, Keshavarz Blvd., corner of Quds St.
City
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Postal code
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Email
vcr@sina.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Seyed Amir Miratashi Yazdi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
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Person responsible for scientific inquiries

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Tehran University of Medical Sciences
Full name of responsible person
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Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
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Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Seyed Amir Miratashi Yazdi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
Street address
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Tehran
Province
Tehran
Postal code
1136746911
Phone
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Email
amiratahi@sina.tums.ac.ir

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
No - There is not a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not 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 entire data will be shared after unidentifying people personal data
When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In order to perform further research with the request from the scientific institute

From where data/document is obtainable

Dear applicants will be referred to Sina Hospital's scientific Center for access to Documents and Data or the applicant can email the project executor. the email address is available. (amiratashi@sina.tums.ac.ir)

What processes are involved for a request to access data/document

After receiving the letter from the project executor, the applicant can refer to Sina Hospital Research Center and after the approval of the executor, the documents and data will be available to executor within a week or the applicant can email directly to project executor so the executor provide the information

Comments