Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Post thyroidectomy hypocalcemia and effects of pre-op calcium supplements on its incidence

Protocol summary

Study aim
To find the post-thyroidectomy hypocalcemia and effects of pre-op calcium supplements on its incidence.

Design
Two arms parallel-group; randomized trial; single-blinded study with placebo with postoperative assessment.

Settings and conduct
Single blind study where participants were blinded not knowing in which group they fall. The study was conducted at CMH Bahawalpur, Bahawalpur, Pakistan.

Participants/Inclusion and exclusion criteria
Inclusion criteria: thyroid swelling whether multinodular or solitary swelling; patients of all ages and genders; patients with normal pre-op calcium levels and with no disease related to calcium levels were included.
Exclusion criteria: patients with deranged calcium levels; patients not undergoing total thyroidectomy; patients with diseases like bone diseases, parathyroid abnormalities, and kidney diseases causing deranged calcium levels; Patients who did not take proper calcium supplements.

Intervention groups
Interventioal Group 1:Giving Pre operative calcium supplements to the patients undergoing total thyroidectomy. In interventional group i made the intervention that gave the patients undergoing surgery pre operatively oral calcium supplements. Interventional group 2: control group. No intervention done.

Main outcome variables
Recovery time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231016059739N1**
Registration date: **2023-12-07, 1402/09/16**
Registration timing: **retrospective**
Last update: **2023-12-07, 1402/09/16**
Update count: **0**

Registration date
2023-12-07, 1402/09/16

Registrant information

Name
Erisha Komal

Name of organization / entity
Combined Military Hospital, Bahawalpur, Pakistan

Country
Pakistan

Phone
+92 62 2501741

Email address
herwithaniphone@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-01, 1401/06/10

Expected recruitment end date
2023-09-30, 1402/07/08

Actual recruitment start date
2022-09-01, 1401/06/10

Actual recruitment end date
2023-09-30, 1402/07/08

Trial completion date
2023-10-10, 1402/07/18

Scientific title
Post thyroidectomy hypocalcemia and effects of pre-op calcium supplements on its incidence

Public title
"Pre-Op Calcium Supplements and Post-Thyroidectomy Hypocalcemia: An Investigative Study”

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
All the pts with thyroid swelling whether multinodular or solitary visiting the hospital Patients of all ages Both genders Patients with normal pre-op calcium levels No disease related to calcium levels
Exclusion criteria:
All the patients with deranged calcium levels Patients not undergoing total thyroidectomy Patients with diseases like bone diseases, parathyroid abnormalities, and kidney diseases causing deranged calcium levels

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **105**
Actual sample size reached: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
I used compluter generated software SPSS for randomization. (I first calculated sample size and then using SPSS randomization was done into 2 groups. Then, each subject was allocated the group accordingly.)

Blinding (investigator's opinion)
Single blinded

Blinding description
We had 2 groups. Both groups were told about the calcium supplements and placebo. one group of patients we gave them tablet cotaining calcium supplements and in the other group we gave them placebo made on order by a phamaceutical company similar to original tablet in shape which did not contained any calcium supplements. Patients were not told which medicines they were given. In this way patiets were blinded and thus my study is single blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Combined Military Hospital Bahwalpur.
Street address
Bahawalpur cantt
City
Bahawalpur
Postal code
63100
Approval date
2023-01-19, 1401/10/29
Ethics committee reference number
ERC Ltr No. 1516/EC/04/2023

Health conditions studied

1

Description of health condition studied
Multinodular goiter and other thyroid diseases
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Post-thyroidectomy hypocalcemia
Timepoint
02 weeks after intervention
Method of measurement
I used lab kit to measure serum calcium levels post operatively.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: contains the patients who receiveed calcium supplements pre operatively.
Category
Treatment - Drugs

2

Description
Interventional group 2: control group who received nothing.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Combined Military Hospital
Full name of responsible person
Dr. Erisha Komal
Street address

Bahawalput cantt
City
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Email
herwithaniphone@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Combined Military hospital, Bahawalpur
Full name of responsible person
Dr. Erisha Komal
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Combined Military hospital, Bahawalpur
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Combined Military Hospital, Bahawalpur
Full name of responsible person
Erisha Komal
Position
Trainee
Latest degree
Bachelor
Other areas of specialty/work
General Surgery
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Title and more details about the data/document

POST THYROIDECTOMY HYPOCALCEMIA AND EFFECTS OF PRE-OP CALCIUM SUPPLEMENTS ON ITS INCIDENCE

When the data will become available and for how long

In january 2024

To whom data/document is available

For people working in institution

Under which criteria data/document could be used

herwithaniphone@gmail.com

From where data/document is obtainable

herwithaniphone@gmail.com

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

By email id

Comments