

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Interventional 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 computer 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 containing calcium supplements and in the other group we gave them placebo made on order by a pharmaceutical 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 patients 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 Bahawalpur.

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 received 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Combined Military hospital, Bahawalpur
Full name of responsible person
Dr. Erisha Komal
Street address
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herwithaniphone@gmail.com

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
Street address

Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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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