Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Post total thyroidectomy hypocalcemia in toxic MNG and effect of post operative intravenous calcium gluconate in its incidence

Protocol summary

Study aim
To see the effectiveness of prophylactic infusion of intravenous calcium gluconate in incidence of post operative hypocalcemia after total thyroidectomy.

Design
Two arm parallel group, single blinded, randomized control trial with post operative intervention and outcome

Settings and conduct
The study was single blinded in which participants were blinded. They were not told in which group they fall. The study will conducted in Combined Military Hospital, Bahawalpur, Pakistan

Participants/Inclusion and exclusion criteria
Patient undergoing total thyroidectomy, having toxic multinodular goiter, having normal pre operative calcium level, having no parathyroid disorder, having no recurrent thyroid disease or willing for part of study were included in study. Patient who were not with toxic multinodular goiter, who were going lobectomy or isthmusectomy only, who were having parathyroid disease, having allergy to calcium gluconate, having deranged pre operative calcium level, taking preoperative calcium supplements, not willing for part of study or whose data could not be maintained were excluded from study.

Intervention groups
In intervention group, preoperative calcium level will be measured and after surgery 1 g of intravenous infusion of calcium gluconate was given (60 minutes infusion) then post op calcium was checked after 12 hours. In control group preoperative calcium level will be measured and after surgery 10 ml normal saline in 100 ml of infusion was given over 60 minutes and post of calcium was checked after 12 hours.

Main outcome variables
Post Operative Calcium level, post operative hypocalcemia duration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240503061640N1**
Registration date: **2024-05-20, 1403/02/31**
Registration timing: **retrospective**

Last update: **2024-05-20, 1403/02/31**
Update count: **0**

Registration date
2024-05-20, 1403/02/31

Registrant information

Name
Muhammad Ahsan Mustafa

Name of organization / entity
CPSP

Country
Pakistan

Phone
+92 333 3396180

Email address
whereisdrahsan@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-15, 1402/07/23

Expected recruitment end date
2024-05-15, 1403/02/26

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Post total thyroidectomy hypocalcemia in toxic MNG and effect of post operative intravenous calcium gluconate in its incidence

Public title
Post total thyroidectomy hypocalcemia in toxic MNG and effect of post operative intravenous calcium gluconate in its incidence

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patient who are with toxic multinodular goiter. Patient who underwent total thyroidectomy. Patient whose pre op calcium level were normal. Pateint who did not have any parathyroid disease. Patient who give consent for study research.

Exclusion criteria:
Patient who are not with toxic multinodular goiter. Patient who have solitary thyroid nodule, hypothyroid, diffuse goiter, thyroid carcinoma and recurrent thyroid swelling. Patient who didn't give consent for study research. Pateint who were not followed. Patient whose pre op calcium were not normal. Patient who were taking pre op calcium supplements. Patient who have parathyroid disease. Pateint who underwent lobectomy and isthmusectomy Patient having any allegy to calcium gluconate.

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **65**

Randomization (investigator's opinion)
Randomized

Randomization description
I used computer generated software SPSS version 23 for randomization. First the sample size was randomized into two groups by using SPSS. Then subjects were assign to each group accordingly.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants were told that they will given post op intravenous calcium gluconate 1 gram 10 ml in 100 ml of infusion as a single dose, or given 10 ml of IV normal saline in 100 ml infusion as a placebo. After informed written consent Patient will be given either medicine post operative. Patient will be told that they will not know which medicine is given to them. As color of both medicine are same, so Patient will not be know which medicine is given. Medicine will be given by resident surgery.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Committee CMH Bahawalpur

Street address
CMH Bahawalpur cantt

City
Bahawalpur

Postal code
63100

Approval date
2023-09-01, 1402/06/10

Ethics committee reference number
1516-EC-01-2023

Health conditions studied

1

Description of health condition studied
Toxic Multinodular goiter and Hypocalcemia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Post total thyroidectomy hypocalcemia

Timepoint
Before and After 12 hours, 24 hours and 48 hour of intervention

Method of measurement
Use laboratory calcium testing machine for measuring calcium level

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group participants pre operative calcium level will be checked by laboratory calcium testing machine. Then total thyroidectomy will be done for toxic MNG. After surgery patient will be given post operative calcium supplements as single dose

intravenous calcium gluconate 1g in 100 ml infusion (in 6 hours). Then post operative calcium levels will be checked after 12, 24 and 48 hours.

Category

Treatment - Drugs

2

Description

Control group: In this group participants pre operative calcium level will be checked by laboratory calcium testing machine. Then total thyroidectomy will be done for toxic MNG. After surgery patient will be given post operative normal saline 10 ml as single dose in 100 ml infusion (in 6 hours). Then post operative calcium levels will be checked after 12, 24 and 48 hours.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Combined Military Hospital

Full name of responsible person
Dr Muhammad Ahsan Mustafa

Street address
CMH Bahawalpur cantt

City
Bahawalpur

Postal code
63100

Phone
+92 333 3396180

Email
whereisdrahsan@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Combined Military Hospital

Full name of responsible person
Muhammad Ahsan Mustafa

Street address
Bahawalpur cantt

City
Bahawalpur

Postal code
63100

Phone
+92 333 3396180

Email
whereisdrahsan@yahoo.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

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Combined Military Hospital Bahawalpur

Full name of responsible person
Dr Muhammad Ahsan Mustafa

Position
Trainee

Latest degree
Bachelor

Other areas of specialty/work
General Surgery

Street address
Bahawalpur cantt

City
Bahawalpur

Province
Punjab

Postal code
63100

Phone
+92 333 3396180

Email
whereisdrahsan@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Combined Military Hospital Bahawalpur

Full name of responsible person
Dr Muhammad Ahsan Mustafa

Position
Trainee

Latest degree
Bachelor

Other areas of specialty/work
General Surgery

Street address
Bahawalpur cantt

City
Bahawalpur

Province
Punjab

Postal code

63100

Phone

+92 333 3396180

Email

whereisdrahsan@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Combined Military Hospital Bahawalpur

Full name of responsible person

Dr. Muhammad Ahsan Mustafa

Position

Trainee

Latest degree

Bachelor

Other areas of specialty/work

General Surgery

Street address

Bahawalpur cantt

City

Bahawalpur

Province

Punjab

Postal code

63100

Phone

+92 333 3396180

Email

whereisdrahsan@yahoo.com

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 TOTAL THYROIDECTOMY HYPOCALCEMIA IN TOXIC MNG AND EFFECT OF POST OPERATIVE INTRAVENOUS CALCIUM GLUCONATE IN ITS INCIDENCE

When the data will become available and for how long

In January 2025

To whom data/document is available

Only available for people working in academic institute

Under which criteria data/document could be used

whereisdrahsan@yahoo.com

From where data/document is obtainable

whereisdrahsan@yahoo.com

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

Through email ID

Comments