

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Study the Effects of Dexamethasone on Prevention of Transient Hypocalcemia after Total Thyroidectomy

Protocol summary

Study aim

Study the Effects of Dexamethasone on Prevention of Transient Hypocalcemia after Total Thyroidectomy

Design

This phase 3 interventional clinical trial will be conducted on 68 patients who are candidates for total thyroidectomy surgery. Patients will be divided into intervention (34 cases) and control (34 cases) groups. In the intervention group, dexamethasone (8 mg) will be injected before total thyroidectomy surgery and 8 and 16 hours after surgery, but subjects in the control group will not receive dexamethasone.

Settings and conduct

68 patients referred to Yasouj hospitals (Imam Sajjad, Shahid Beheshti and Jalil) who are awaiting total thyroidectomy surgery due to thyroid tumor, goiter, treatment-resistant hyperthyroidism, and unilateral thyroid lobectomy will be included in the study and divided into intervention (34 cases) and control (34 cases) groups. In the intervention group, dexamethasone (8 mg) will be injected before total thyroidectomy surgery and 8 and 16 hours after surgery. Subjects in the control group will not receive dexamethasone. The serum calcium level of all patients will be measured every twelve hours for two days. The calcium level less than 8 is considered as hypocalcemia and the patient is treated with oral calcium.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients aged 18 to 70 years, who are candidates for total thyroidectomy surgery due to thyroid tumor, goiter, treatment-resistant hyperthyroidism, and unilateral thyroid lobectomy Exclusion Criteria: Patients with Diabetes or Hypertension Patients who have take Cortone for more than 7 days in the last three months Pregnant subjects

Intervention groups

Intervention group: intravenous injection of dexamethasone (8 mg) before total thyroidectomy surgery and 8 and 16 hours after surgery Control group:

no dexamethasone injection

Main outcome variables

Measurement of Serum Calcium Level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230529058331N1**

Registration date: **2023-07-03, 1402/04/12**

Registration timing: **prospective**

Last update: **2023-07-03, 1402/04/12**

Update count: **0**

Registration date

2023-07-03, 1402/04/12

Registrant information

Name

Mohammad Ostovari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 7230

Email address

mo.ostovari82@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Study the Effects of Dexamethasone on Prevention of Transient Hypocalcemia after Total Thyroidectomy

Public title
Effects of Dexamethasone on Hypocalcemia after Thyroidectomy

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are candidates for total thyroidectomy surgery due to thyroid tumor, goiter, treatment-resistant hyperthyroidism, and unilateral thyroid lobectomy
Patients aged between 18 to 70 years old
Patients who have given written consent to participate in the study
Exclusion criteria:
Patients with Diabetes
Patients with Hypertension
Patients who have take Cortone for more than 7 days in the last three months
Pregnant subjects

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yasuj University of Medical Sciences

Street address

Kohgiluyeh and Boyer-Ahmad Province, Yasuj, Shahid Motahari Blvd

City

Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
75917-41417

Approval date

2023-05-29, 1402/03/08

Ethics committee reference number

IR.YUMS.REC.1401.169

Health conditions studied

1

Description of health condition studied

Total Thyroidectomy Surgery

ICD-10 code

E07.9

ICD-10 code description

Disorder of thyroid, unspecified

Primary outcomes

1

Description

Measurement of Hypocalcemia

Timepoint

The serum calcium level will be measured every twelve hours for two days in both of the intervention and control groups.

Method of measurement

Venous blood samples will be taken from patients at designated times. After serum separation, the serum calcium level will be measured in all patients. The calcium level less than 8 is considered as hypocalcemia and the patient is treated with oral calcium. Collected data will be analyzed using SPSS software version 21. Descriptive statistics, frequency distribution tables and graphs will be used to describe the data.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, dexamethasone (8 mg) will be injected before total thyroidectomy surgery and 8 and 16 hours after surgery. The serum calcium level of all patients will be measured every twelve hours for two days. A calcium level less than 8 will be considered as hypocalcemia and the patient will be treated with oral calcium.

Category

Prevention

2

Description

Control group: Subjects in the control group will not receive dexamethasone, but the serum calcium level of all patients will be measured every twelve hours for two days. A calcium level less than 8 will be considered as hypocalcemia and the patient will be treated with oral calcium.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Government Hospitals of Yasouj City (Imam Sajjad, Shahid Beheshti, and Jalil).

Full name of responsible person

Mohammad Ostovari

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Kohgiluyeh and Boyer-Ahmad Province, Yasuj, Shahid Motahari Blvd

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Email

mo.ostovari82@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Seyed Amin Hossaini Motlagh

Street address

Kohgiluyeh and Boyer-Ahmad Province, Yasuj, Shahid Motahari Blvd, Yasuj University of Medical Sciences

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aminhomo@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Mohammad Ostovari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

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Full name of responsible person

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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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be 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

Patients are requested to read and sign the written consent form. Then, the demographic data including age, gender, histological diagnosis, pathology results and other relevant data will be collected and recorded. Subjects will be divided into two control and intervention groups and the designed experiments will be performed. At the end of the study, the obtained data will be analyzed and published in an article.

When the data will become available and for how long

The access period starts from 2024

To whom data/document is available

Researchers

Under which criteria data/document could be used

Researches

From where data/document is obtainable

Dr. Mohammad Ostovari mo.ostovari82@yahoo.com

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

After the article is published, it is possible to access the data.

Comments