Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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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

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Person responsible for scientific inquiries

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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
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