

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effect of topical dexamethasone at the site of thyroid surgery (on the parathyroids) on blood calcium levels after surgery, compared to the control group in patients who underwent total thyroidectomy.

Protocol summary

Study aim

Investigating the effect of topical dexamethasone in the thyroid surgery site (on the parathyroids) on blood calcium levels after surgery, compared to the control group in patients who underwent total thyroidectomy.

Design

Clinical trial with control group, with parallel groups, randomized, phase 3 on 60 patients. A table of random numbers was used for randomization.

Settings and conduct

The current study is a randomized clinical trial with a before and after design. The statistical population under investigation is all total thyroidectomy candidate patients referred to Imam Khomeini Hospital in 1401, who will be divided into two groups of 30 people using a random number table after determining the inclusion and exclusion criteria. In the case group, after thyroidectomy in the same operating room, an ampoule of dexamethasone (8 mg-2 ml) will be sprayed at the thyroidectomy site, and no special action will be taken in the control group. The investigated times will be before thyroidectomy, 6 hours, 24 hours and 48 hours after thyroidectomy. The data collection tool is a questionnaire, and the data will be entered into SPSS version 22 software after collection.

Participants/Inclusion and exclusion criteria

Inclusion: patients with confirmed thyroid cancer, do not take calcium containing drugs and any corticosteroid drugs, have no history of thyroid or parathyroid surgery. Exclusion: Patients who needed re-operation before 48 hours due to surgical complications such as hematoma at the operation site.

Intervention groups

In the case group, after thyroidectomy in the same operating room, an ampoule of dexamethasone (8 mg-2 ml) will be sprayed at the thyroidectomy site, and no

special action will be taken in the control group. The times examined in our study will be before thyroidectomy, 6 hours, 24 hours and 48 hours after thyroidectomy.

Main outcome variables

Blood calcium level.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230323057764N1**

Registration date: **2023-05-10, 1402/02/20**

Registration timing: **prospective**

Last update: **2023-05-10, 1402/02/20**

Update count: **0**

Registration date

2023-05-10, 1402/02/20

Registrant information

Name

Seyyed Mohammad Hossein Mousavi Beyuki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5724 8098

Email address

txhosseinmoosavi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01
Expected recruitment end date
2023-08-23, 1402/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of topical dexamethasone at the site of thyroid surgery (on the parathyroids) on blood calcium levels after surgery, compared to the control group in patients who underwent total thyroidectomy.

Public title
The effect of local spraying of dexamethasone in the thyroid site after thyroidectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with confirmed thyroid cancer who need total thyroidectomy Patients who do not take calcium-containing drugs Patients who do not use any corticosteroid medication Patients who had no history of thyroid or parathyroid surgery
Exclusion criteria:
Patients who require re-operation before 48 hours due to surgical complications such as hematoma at the operation site

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the sample size is 60 people, which is less than 100. If people are divided between 2 groups by simple random method. According to the rule of randomization of taps and lines, the number of taps and lines may not be equal in two groups. Therefore, the Block-Randomization method is used. The sample size calculated in this study is 30 people in each group. Therefore, 10 blocks of 4 people are formed and 5 blocks are randomly assigned to each group. As a result, the balance between the two groups is allocated in the form of 30 people to one group and another 30 people to the second group. A simple random method is used to assign people to each block. It means that people are placed in one of these blocks based on a table of random numbers

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 Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences Headquarters, Qods Corner, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2023-03-15, 1401/12/24

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.452

Health conditions studied

1

Description of health condition studied

Investigating the effect of topical dexamethasone at the site of thyroid surgery (on the parathyroids)

ICD-10 code

E21.4

ICD-10 code description

Other specified disorders of parathyroid gland

Primary outcomes

1

Description

Blood calcium level

Timepoint

Before thyroidectomy

Method of measurement

Based on the patient's file

Secondary outcomes

1

Description

Blood calcium level

Timepoint

Before thyroidectomy, 6 hours, 24 hours and 48 hours after thyroidectomy

Method of measurement

Based on the patient's file

Intervention groups**1****Description**

Intervention group: after performing thyroidectomy in the same operating room, an ampoule of dexamethasone (8 mg-2 ml) will be sprayed at the thyroidectomy site.

Category

Treatment - Drugs

2**Description**

Control group: no special action will be taken after thyroidectomy.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital Complex

Full name of responsible person

Seyyed Mohammad Hossein Mousavi Beyuki

Street address

Imam Khomeini Hospital Complex, Dr. Gharib Street, at the end of Keshavarz Boulevard, Tehran.

City

Tehran

Province

Tehran

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1419733141

Phone

+98 21 6405 3334

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Imamhospital@tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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Imam Khomeini Hospital Complex, at the end of Keshavarz Boulevard, Dr. Gharib Street, Tehran.

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afotouhi@tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Iran University of Medical Sciences

Full name of responsible person

Seyyed Mohammad Hossein Mousavi Beyuki

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Fax**Email**

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Seyyed Mohammad Hossein Mousavi Beyuki

Position

Resident

Latest degree

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Other areas of specialty/work

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

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

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Seyyed Mohammad Hossein Mousavi Beyuki

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address