

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effect of dexamethasone local injection during thyroidectomy on postoperative complications: A clinical trial

Protocol summary

Study aim

Determining the effect of local dexamethasone injection during thyroidectomy surgery on postoperative complications

Design

A controlled, parallel-group, triple-blinded, randomized, phase 3 clinical trial on 150 patients. Computer random number method was used for randomization.

Settings and conduct

The type of study is a triple-blind clinical trial (patient, researcher, data analyst) and its place is the educational-therapeutic centers of Isfahan city. The patient and the person collecting the data are not aware of their group, and the sealed envelope is presented to the surgeon in the operating room.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are candidates for total thyroidectomy surgery, having no history of neck radiation therapy Exclusion criteria: previous neck surgeries

Intervention groups

In the systemic dexamethasone group, 8 mg of dexamethasone is injected intravenously immediately before the operation and after induction of anesthesia. In the local dexamethasone group and the control group, the amount of 8 mg of dexamethasone and 8 mg of normal saline will be injected in the operation field after the end of the operation and before closing the operation field.

Main outcome variables

Calcium level the day after surgery; Postoperative pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220916055970N1**

Registration date: **2023-02-13, 1401/11/24**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-13, 1401/11/24**

Update count: **0**

Registration date

2023-02-13, 1401/11/24

Registrant information

Name

Hossein Moeini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

hosseinmoeini6788@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-05, 1401/10/15

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of dexamethasone local injection during thyroidectomy on postoperative complications: A clinical trial

Public title

The effect of dexamethasone local injection during

thyroidectomy on postoperative complications

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidates for total thyroidectomy surgery No previous surgeries in the neck area No history of radiation therapy in the neck area

Exclusion criteria:

Previous surgeries in the neck area

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyst

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be placed in blocks of three based on their hospital admission number (for example, numbers 1 to 3 in the first block, numbers 4 to 6 in the second block, and so on). Then in each block based on the table of random numbers 1-9, if the number of 1-3 is selected, the desired person will be assigned to group A, if the number of 4-6 is selected, the desired person will be assigned to group B, and if the number of 7-9 is selected, the desired person will be assigned to group C. Obviously, in one block, if repeated numbers are selected, the number selection will be repeated so that the person enters a different group. At the end, in the same way, groups A, B, and C will be assigned to three groups: systemic dexamethasone, topical dexamethasone, and the control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient, the researcher, and the person collecting the data are not informed of their group, and the sealed envelope is presented to the surgeon in the operating room

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Building No. 4, Hezar Jerib St., Isfahan University of Medical Sciences and Health Services

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-06-06, 1401/03/16

Ethics committee reference number

IR.MUI.MED.REC.1401.103

Health conditions studied

1

Description of health condition studied

Thyroidectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Calcium level after surgery

Timepoint

12 and 24 hours after the operation

Method of measurement

Blood test

2

Description

Postoperative pain score

Timepoint

24 hours after the operation

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the systemic dexamethasone group, 8 mg of dexamethasone (DEXAMETHASONE AMP, ALBORZDAROU, 8MG/2ML) was injected intravenously

immediately before the operation and after induction of anesthesia.

Category

Prevention

2**Description**

Intervention group: In the local dexamethasone group, after the end of the operation and before closing the operation field, 8 mg of dexamethasone (DEXAMETHASONE AMP, ALBORZDAROU, 8MG/2ML) will be injected into the operation field.

Category

Prevention

3**Description**

Control group: In the control group, after the operation and before closing the operation field, 8 mg of normal saline (SODIUM CHLORIDE Serum, ALBORZDARU, 0.45% & 1L) will be injected in the operation field.

Category

Placebo

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

Alzahra Hospital

Full name of responsible person

Hossein Moeini

Street address

Alzahra Hospital, Sofeh Blvd.

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

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash

Street address

Building No. 4, Vice Chancellor for Research and Technology, Hezar Jerib St., Isfahan University of Medical Sciences and Health Services

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research@mui.ac.ir

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

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Hossein Moeini

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Alzahra Hospital, Sofeh Blvd.

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Phone

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

Esfahan University of Medical Sciences

Full name of responsible person

Hossein Moeini

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Information is kept confidential.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

Not applicable

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

After publishing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Using data to complete studies

From where data/document is obtainable

Dr. Hossein Moeini, Isfahan University of Medical Sciences

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

By examining the researcher's request and providing sufficient documentation of his research and the reason for using the data can be provided.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Hossein Moeini

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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