

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Dec 2023

Effect of perioperative intravenous dexamethasone on hypocalcemia after total thyroidectomy in patients who candidate for thyroidectomy

Protocol summary

Summary

This study aims to focus on effect of perioperative intravenous dexamethasone on hypocalcemia after total thyroidectomy. In prospective randomized unblinded study, 90 subjects who needs total thyroidectomy is entered. They divided in two groups: 45 patients receive 8mg Dexamethasone 90 minutes before surgery as case groups and 45 patients do not as control group. patients with age range 18-70 years who need total thyroidectomy are included. Patients who have History of corticoesteroid consumption in past three months are excluded. Hypocalcemia is compared after surgery in both.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011329726N3**

Registration date: **2017-02-10, 1395/11/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

Mohsen Kolahdouzan

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of perioperative intravenous dexamethasone on hypocalcemia after total thyroidectomy in patients who candidate for thyroidectomy

Public title

Effect of perioperative intravenous dexamethasone on hypocalcemia after total thyroidectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age range 18-70 years; needed total thyroidectomy; tendency for participation in the study
Exclusion criteria: diabetic patients; history of ischemic heart disease; hypertensive patients; History of corticoesteroid consumption in past three months; pregnancy; addiction; expired patients during study; any changes in thyroidectomy types

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

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

Ethic Committee of Isfahan University of Medical Sciences

Street address

Floor 2, Office of Deputy President, Isfahan, Isfahan University of Medical Sciences, Hezarjarib Ave,

City

Isfahan

Postal code

8174673461

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

393921

Health conditions studied

1

Description of health condition studied

Hypocalcemia

ICD-10 code

E89.2

ICD-10 code description

Other postprocedural endocrine and metabolic disorders

Primary outcomes

1

Description

serum Ca Level

Timepoint

6 and 24 hours after surgery

Method of measurement

Blood sampling

2

Description

Serum PTH level

Timepoint

6 and 24 hours after surgery

Method of measurement

Blood sampling

Secondary outcomes

1

Description

Clinical symptoms of Hypocalcemia

Timepoint

Two weeks after surgery

Method of measurement

History taking and physical examination

Intervention groups

1

Description

Case group: receive Dexamethasone 8mg 90 minutes before total thyroidectomy

Category

Prevention

2

Description

Control Group: without Dexamethasone before thyroidectomy

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Mohsen Kollahdouzan

Street address

Surgery Department, Alzahra Hospital, Soffeh Avenue, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Mehdi Nematbakhsh

Street address

Vice chancellor for Research, Soffeh Avaneue, Isfahan
University of Medical Sciences, Isfahan, Iran

City

Isfahan

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

Yes

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Isfahan University of Medical Sciences

Full name of responsible person

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Position

Faculty Member

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty