

# 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

+98 31 3669 2277

###### Email address

kolahdouzan@med.mui.ac.ir

##### 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 Kolahdouzan

##### 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**

Mohsen Kollahdouzan

**Position**

Faculty Member

**Other areas of specialty/work****Street address**

Surgery Department, Alzahra Hospital, Soffeh  
Avenue, Isfahan,

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**Phone**

+98 31 3620 2020

**Fax****Email**

kolahdouzan@med.mui.ac.ir

**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*