

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Effect of preoperative intravenous Dexamethasone on voice change after total thyroidectomy

Protocol summary

Summary

The main idea of study is to evaluate the effect of preoperative intravenous Dexamethasone on voice change after thyroidectomy. We designed a double blind randomized clinical trial. Patients with total thyroidectomy are enrolled. Exclusion criteria are reoperation and preoperative voice change. Patients are randomized into two groups. For each patient two questionnaires will be filled. One questionnaire contains demographic data, thyroid pathology, thyroid weight, wound infection and healing rate and blood glucose level on days one and seven after surgery. The other questionnaire is for voice change containing 10 questions each scoring 0-4 which will be filled by patients preoperatively and on days one and seven after surgery. After informed consent, one hour before surgery, one group will receive 8 mg (2 cc) Dexamethasone intravenously and the other group will receive 2 cc normal saline as placebo. The information will be analyzed by SPSS and voice change will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106306925N1**

Registration date: **2012-02-18, 1390/11/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-02-18, 1390/11/29

Registrant information

Name

Shirzad Nasiri

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2450

Email address

nasiri@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2011-06-22, 1390/04/01

Expected recruitment end date

2012-06-20, 1391/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of preoperative intravenous Dexamethasone on voice change after total thyroidectomy

Public title

Effect of Dexamethasone on voice change after total thyroidectomy

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: total thyroidectomy patients exclusion criteria: prior operation; voice change preoperatively

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 66

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences Ethics Committee

Street address

6 th floor, central building of Tehran University of Medical Sciences, Gods st., Keshavarz ave.

City

Tehran

Postal code

Approval date

2011-06-19, 1390/03/29

Ethics committee reference number

130/1313/3

Health conditions studied

1

Description of health condition studied

total thyroidectomy

ICD-10 code

Y83.6

ICD-10 code description

Removal of other organ (partial) (total)

Primary outcomes

1

Description

voice change

Timepoint

Before operation and 1 and 7 days after surgery

Method of measurement

questionnaire

Secondary outcomes

1

Description

wound infection

Timepoint

1 st and 7 th days after surgery

Method of measurement

Physical examination

2

Description

Blood glucose level

Timepoint

1 st and 7 th days after surgery

Method of measurement

Lab analysis

Intervention groups

1

Description

8 mg of dexamethasone intravenously before induction of anesthesia.

Category

Treatment - Drugs

2

Description

2 cc of normal saline intravenously before induction of anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital, general surgery ward

Full name of responsible person

Dr. Shima Shafag

Street address

General surgery ward, Shariati Hospital, North Kargar st.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Fotuhi

Street address

Tehran University of Medical Sciences building, Gods st., Keshavarz ave.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Shima Shafag

Position

General surgery resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Assistant professor of surgery

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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