

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 inform 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 thyroidecyomy
ICD-10 code
Y83.6
ICD-10 code description
Removal of other organ (partial) (total)

Primary outcomes

1
Description
voice change
Timepoint
Befor operation and 1 and 7 days after surgery
Method of measurement
quetionnaire

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 inrtavenously befor induction of anesthesia.
Category
Treatment - Drugs

2
Description
2 cc of normal salin intravenously befor 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 Shafagh

Position

General surgery resident

Other areas of specialty/work

Street address

Shariati Hospital, North Kargar st.

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shafagh824@yahoo.com

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant professor of surgery

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences, Shariati Hospital

Full name of responsible person

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Position

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Other areas of specialty/work

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City

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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