

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of compliations of thyroid surgery with and without drain

Protocol summary

Summary

Patients that are candidate for thyroid surgery are divided into 2 groups: total- subtotal thyroidectomy and thyroid lobectomy. Each group is randomized into "drain" and "non drain" branch . complications in each group is assesed between drain and nondrain group. target sample size is 50 patients. inclusion criteria is patients eligible for total- subtotal thyroidectomy or thyroid lobectomy based on scientific guidelines. Exclusion criteria is Coagolation disorders,Substernal throid and Cervical lymph node dissection. Study variables are patients age,gender ,preoperative thyroid size and postoperative complications like postoperative wound site hematoma ,infection,need for postoperative drainage. These complications are detected by surgical attending and surgical residents early after surgery and at first postoperative visit and are evaluated by statistical metods .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112118373N1**

Registration date: **2012-01-28, 1390/11/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-01-28, 1390/11/08

Registrant information

Name

Seyed Amin Madani

Name of organization / entity

Ahvaz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 912 545 2538

Email address

madani.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz University of Medical Science

Expected recruitment start date

2010-12-22, 1389/10/01

Expected recruitment end date

2012-05-21, 1391/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of compliations of thyroid surgery with and without drain

Public title

Effects of drain placement after thyroid surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : patients eligible for total- subtotal thyroidectomy or thyroid lobectomy based on scientific guidelines. Exclusion criteria : Coagolation disorders,Substernal throid and Cervical lymph node dissection.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

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

Ahvaz University of Medical Science

Street address

Ahvaz University of Medical Science-Research Centre

City

Ahvaz

Postal code

Approval date

2011-10-01, 1390/07/09

Ethics committee reference number

eth-247

Health conditions studied

1

Description of health condition studied

Iodine deficiency related thyroid disorders

ICD-10 code

E01

ICD-10 code description

Iodine deficiency related thyroid disorders

2

Description of health condition studied

non toxic goiter

ICD-10 code

E04

ICD-10 code description

Nontoxic goiter

Primary outcomes

1

Description

wound site hematoma

Timepoint

during hospitalization and first postoperation visit

Method of measurement

evaluation by a surgeon or surgical resident

2

Description

need for surgical drainage of hematoma

Timepoint

during hospitalization and first postoperation visit

Method of measurement

evaluation by a surgeon or surgical resident

3

Description

surgical site infection

Timepoint

during hospitalization and first postoperation visit

Method of measurement

evaluation by a surgeon or surgical resident

4

Description

voice change after operation

Timepoint

during hospitalization and first postoperation visit

Method of measurement

evaluation by a surgeon or surgical resident

5

Description

postoperative dyspnea

Timepoint

during hospitalization and first postoperative visit

Method of measurement

evaluation by surgeon or surgical resident

6

Description

postoperative dysphagia

Timepoint

during hospitalization and first postoperative visit

Method of measurement

evaluation by surgeon or surgical resident

Secondary outcomes

1

Description

duration of hospital stay

Timepoint

from admission until discharge

Method of measurement

number of days the patient stays in hospital

Intervention groups

1

Description

Drain is inserted in intervention arm . Patinents are candidate for total-subtotal thyroidectomy or thyroid lobectomy. Drain type is vacuum assisted and is taken out depending postoperative condition.

Category

Treatment - Surgery

2

Description

In control arm ,we dont insert any drain. paitients are discharged based on postoperative evaluation.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Amin Madani M.D.

Street address

Saat Square, Amanieh , Razi hosoidal

City

Ahvaz

2

Recruitment center

Name of recruitment center

Emam Khomeyni hospital

Full name of responsible person

Amin Madani M.D.

Street address

Azadegan street, Emam Khomeyny hospital

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Science Research Center

Full name of responsible person

Mostafa Fegghi M.D.

Street address

Jondi Shahpoor University, Golestan street,

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz University of Medical Science Research Center

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

Ahvaz Univrsity of Medical Science

Full name of responsible person

Amin Madani M.D.

Position

surgical resident

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Postal code**Phone**

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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