

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trials comparison of complications of thyroid surgery with and without drain

Protocol summary

Summary

The aim of this study was to evaluate the outcome of thyroid surgery with and without drains in patients undergoing total or subtotal or lobectomy of thyroid surgery. 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 assessed between drain and nondrain group. The sample size is 180 patients. Inclusion criteria for the study, patients undergoing total or subtotal or lobectomy of thyroid surgery. Exclusion criteria retrosternal thyroid, lymph node neck dissection; coagulopathy. These complications include wound related complications such as wound infection and hematoma at the site of action or duration of hospitalization and other complications such as hematoma is required to transfer to the operating room are looking for. The hemovac drain is used and if drainage is less than 30 cc out in 24 hours the drain exited. In the first, the third and the Thirtieth postoperative day, the site of surgery is examined for bleeding, hematoma, seroma and wound infection (redness, swelling, heat, pain, fever and infectious secretions).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030319255N4**
Registration date: **2016-06-08, 1395/03/19**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-08, 1395/03/19

Registrant information

Name

Novin Nikbakhsh

Name of organization / entity

Babol University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Expected recruitment start date

2013-01-01, 1391/10/12

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

Clinical trials comparison of complications of thyroid surgery with and without drain

Public title

Evaluation of thyroid Surgery Outcomes with and without drain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with a diagnosis of thyroid cancer; Multinodular goiter and thyroid nodules; undergoing total or subtotal or lobectomy of thyroid

surgery . Inclusion criteria: patients with a diagnosis of thyroid cancer; Multinodular goiter and thyroid nodules; undergoing total or subtotal or lobectomy of thyroid surgery . pleased to participate in the study; Exclusion criteria were: if patients in the preoperative studies, have an underlying disease (diabetes, cardiovascular disease, etc.); congenital; acquired bleeding disorder; retrosternal thyroid; patients who underwent modified or radical neck dissection or forced to devise the drains were during surgery

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In this study, 180 patients have been assigned to two groups of intervention and control with using random numbers table

Secondary Ids**1****Registry name**

www.mubabol.ac.ir

Secondary trial Id

MUBABOL.REC.13940290

Registration date

1994-11-06, 1373/08/15

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences- Ganjafrooz Street- Babol- Iran

City

Babol

Postal code**Approval date**

2015-09-28, 1394/07/06

Ethics committee reference number

30/6636/ز/پ

Health conditions studied**1****Description of health condition studied**

Thyroid diseases caused by iodine deficiency

ICD-10 code

E01

ICD-10 code description

Iodine deficiency related thyroid disorders

Primary outcomes**1****Description**

Hematoma surgery

Timepoint

Hospitalization time and first postoperative visit

Method of measurement

Evaluation by surgeon or surgical resident

2**Description**

Infection surgery

Timepoint

Hospitalization time and first postoperative visit

Method of measurement

Evaluation by surgeon or surgical resident

Secondary outcomes**1****Description**

Need surgery to drain the hematoma

Timepoint

Hospitalization time and first postoperative visit

Method of measurement

Clinical diagnosis of assistant surgeon or surgical resident

Intervention groups**1****Description**

In intervention group, the patients that are condidated for total or subtotal or lobectomy of thyroid surgery is drained.The hemovac drain is passed from below the neck incision. Based on the patient's condition and the amount of fluid; decide to bring out in the days after the operation.

Category

Treatment - Surgery

2

Description

In the control group after thyroid surgery is not drained. Patients are examined days after surgery and are discharged on the basis of general conditions.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Shahid Beheshti Hospital

Full name of responsible person

Dr. Novin Nikbakhsh

Street address

Babol University of Medical Sciences- Ganjafrooz
Street- Babol- Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Babol
University of Medical Sciences

Full name of responsible person

Dr. Aliakbar Moghaddamnia

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Babol University of Medical Sciences- Ganjafrooz
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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 and Technology, Babol
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

Babol University of Medical Sciences

Full name of responsible person

Dr. Asgari Abbaszadeh

Position

Resident of General Surgery

Other areas of specialty/work

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Person responsible for updating data

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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