Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 surgury are devided 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 beteween 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/پ/ژ

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 surgen or surgical resident

2

Description
Infection surgery

Timepoint
Hospitalization time and first postoperative visit

Method of measurement
Evaluation by surgen 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 intervation 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
City
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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
Street address
Babol University of Medical Sciences- Ganjafrooz Street- Babol- Iran
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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
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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