

# 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

Iran (Islamic Republic of)

##### Phone

+98 11 3225 6285

##### Email address

n.nicbakhsh@mubabol.ac.ir

#### 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

##### City

Babol

## 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

##### City

Babol

#### 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

#### Street address

Babol University of Medical Sciences- Ganjafrooz  
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Babol

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Babol University of Medical Sciences

#### Full name of responsible person

Dr. Novin Nikbakhsh

#### Position

Associated Professor of Surgery

#### Other areas of specialty/work

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## Person responsible for updating data

### 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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#### 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*