

# Is routine drainage necessary after thyroid surgery - a randomised controlled trial

<b>Submission date</b> 31/01/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/02/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/08/2009	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
N/A

## Study information

## **Scientific Title**

### **Study objectives**

To study the role of drains after thyroid surgery and monitor the fluid collection in thyroid bed.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Randomised controlled parallel group trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Thyroid disorders

### **Interventions**

All patients included in the study were randomly allocated to drain and non-drain group on the basis of computer generated random number table. The surgeon was informed of the group just before the closure of the wound. In the drain group a closed suction drain with negative pressure (Romovac®) was brought out through a separate wound. Ultrasound of the neck using B mode with linear frequency of 7.5 MHz was performed in both groups between 24 to 48 hours of surgery and seventh postoperative day. Volume of fluid collection in the operative bed was calculated by measuring the maximum diameter in three dimensions. The volume of fluid collected in the suction drain was measured separately. The drains were removed in all the patients after 48 hours. All patients were observed for any postoperative respiratory distress, change in voice, wound collection, tingling sensation, tetany etc.

### **Intervention Type**

Procedure/Surgery

### **Phase**

Not Specified

### **Primary outcome measure**

All patients were observed for any postoperative respiratory distress, change in voice, wound collection, tingling sensation, tetany etc. The specimens were subjected to histopathological examination for final confirmation of diagnosis. Using two sample t-test all the data was statistically analyzed for any significant difference in the two groups for:

1. Fluid collection in thyroid bed on day one and day seven
2. Size of nodule and amount of fluid collection
3. Complication rate

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

01/01/2001

### **Completion date**

01/03/2002

## **Eligibility**

### **Key inclusion criteria**

The study was carried out on 94 patients who underwent thyroid surgeries in a single unit. Patients with cervical lymph nodes metastases requiring neck dissection and those with clinical or laboratory indicators of coagulation disorders were excluded from the study. No patient was excluded on the basis of size of the gland, difficulty in surgery, surgery involving both lobes and re-operation in the neck.

### **Participant type(s)**

Patient

### **Age group**

Not Specified

### **Sex**

Not Specified

### **Target number of participants**

94

### **Key exclusion criteria**

Does not match inclusion criteria

### **Date of first enrolment**

01/01/2001

### **Date of final enrolment**

01/03/2002

## **Locations**

### **Countries of recruitment**

India

**Study participating centre**  
DII/131, West Kidwai Nagar  
New Delhi  
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## Sponsor information

**Organisation**  
Safdarjung Hospital - Vardhman Mahavir Medical College (India)

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**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.vmmc-sjh.nic.in/>

**ROR**  
<https://ror.org/03zj0ps89>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Safdarjung Hospital - Vardhman Mahavir Medical College (India) - a government aided institution

## Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Results	19/05/2005		Yes	No