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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
31/01/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
04/02/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
24/08/2009	Surgery			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Chintamani

Contact details

DII/131, West Kidwai Nagar New Delhi India 110023 +91 (0)11 26886405 chintamani7@rediffmail.com

Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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 India 110023

Sponsor information

Organisation

Safdarjung Hospital - Vardhman Mahavir Medical College (India)

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

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?
Results article	Results	19/05/2005		Yes	No