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

Submission date	Recruitment status	[_] Prospectively registered
31/01/2005	No longer recruiting	[_] 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

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

Primary study design
Interventional

Study design
Randomised controlled parallel group trial

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