

Is the routine Pressure Dressing After Thyroidectomy necessary? A prospective randomised controlled study

Submission date 12/11/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/02/2019	Condition category 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
NCT00400465

Secondary identifying numbers

N/A

Study information

Scientific Title

Is the routine Pressure Dressing After Thyroidectomy necessary? A prospective randomised controlled study

Acronym

PDAT

Study objectives

Thyroidectomy is an operation that is commonly performed. After an operation a pressure dressing by Hypafix is usually used due to the belief that it will help to reduce complications such as post-operative bleeding or haematoma. However, the practice is uncomfortable to patients and makes it hard to detect early haematomas.

We carried out a prospective randomised study to study the role of pressure dressing after thyroid surgery by evaluating the amount of fluids collected in the operative bed by ultrasonography compared with normal dressing.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval was gained from the ethics committee of Khon Kaen University on the 22nd November 2006 (ref: HE491009).

Study design

Randomised single-blind controlled study

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

Post-operative bleeding, haematoma

Interventions

After the thyroidectomy was performed, patients were randomised to one of the following groups:

1. Control group: pressure dressings
2. Experimental group: normal dressings

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

Amount of fluids collected in the thyroid bed by ultrasonography

Secondary outcome measures

1. Days retained drains
2. Days of hospital stay
3. Complications (bruise, bleeding, wound dehiscence)

Overall study start date

01/12/2006

Completion date

31/12/2007

Eligibility

Key inclusion criteria

Patients undergoing thyroidectomy in Srinagarind Hospital (Thailand)

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

114

Key exclusion criteria

1. Cervical lymph node metastases requiring neck dissection
2. Tissue pathology that showed anaplastic carcinoma
3. Clinical or laboratory indicators of coagulation disorders

Date of first enrolment

01/12/2006

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

Thailand

Study participating centre**Department of Otolaryngology**

Khon Kaen

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Sponsor information

Organisation

Khon Kaen University (Thailand)

Sponsor details

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Sponsor type

University/education

Website

<http://www.kku.ac.th/eng/>

ROR

<https://ror.org/03cq4gr50>

Funder(s)

Funder type

University/education

Funder Name

Khon Kaen University (Thailand) - Faculty of Medicine (internally funded)

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?
Results article	results	20/03/2008	01/02/2019	Yes	No