ISRCTN94715414 https://doi.org/10.1186/ISRCTN94715414

Drains should be abandoned following thyroid surgery

Submission date	Recruitment status	[_] Prospectively registered
18/03/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/03/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/01/2013	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A prospective double-blinded randomised clinical trial evaluating the impact of drain insertion versus no drain insertion following thyroid surgery on patient outcome

Study objectives
Drain insertion routinely inserted following thyroid surgery does not benefit patient outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of University College Cork (Ireland) approved on the 2nd January 2008 (ref: ECM 3 (dd) 05/02/08)

Study design
Double-blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Thyroid surgery

Interventions
Patients are randomised to drain or no drain insertion at the end of surgery. Patients undergo ultrasound 24 and 48 hours post-operatively.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Fluid accumulation in thyroid bed 24 hours post-operatively

Secondary outcome measures

1. Length of post-operative stay
2. Pain using a visual analogue scale
3. Analgesia requirements at 24 hours
4. Fluid accumulated on ultrasound at 48 hours

Overall study start date
01/01/2008

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Patients aged 18 - 79 years, either sex
2. Undergoing thyroidectomy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
93

Key exclusion criteria
1. Sternotomy
2. Neck dissection
3. Less than 18 years
4. History of bleeding disorders

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Ireland

Study participating centre
Department of Surgery
Cork
Ireland
-

Sponsor information

Organisation
Cork University Hospital (Ireland)

Sponsor details
c/o Professor Paul Redmond
Department of Academic Surgery
University College Cork
Wilton
Ireland
-

Sponsor type
Not defined

Website
http://www.cuh.hse.ie/

ROR
https://ror.org/04q107642

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Ireland)

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	28/04/2012		Yes	No