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Does antithrombotic prophylaxis increase the incidence of post-operative bleeding and duration of post-operative hospital stay after thyroidectomy? A retrospective study

Submission date
23/01/2018

Recruitment status
No longer recruiting

Registration date
05/02/2018

Overall study status
Completed

Last Edited
13/05/2019

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Providing antithrombotic medication (drugs that reduce the change of blood clots) during surgery could help prevent blood clots and pulmonary embolism (blocking of a bloog vessel in the lung), however this increases the risk of bleeding after surgery. This topic has not been adequately investigated in thyroid surgery. In thyroid surgery, even a small bleeding may result in airway compression and death by asphyxia (a lack of oxygen). The aim of this study is to establish whether providing antithrombotic drugs during surgery can negatively affect the early outcome of patients undergoing total thyroidectomy, with particular reference to the incidence of bleeding and duration of post-operative hospital stay. Therefore this study aims to clarify if antithrombotic drugs administered in order to prevent thromboembolic events are safe and effective in thyroid surgery.

Who can participate?
Adults aged 18 and older who are having a thyroid surgery.

What does the study involve?
Participants underwent thyroidectomy and antithrombotic drugs according with standard surgical criteria and international guidelines for antithrombotic prophylaxis. All patients are subject to a close monitoring in the first 12 hours after surgery and, after discharge, are re-evaluated within 1 week in order to assess the wound and, if appropriate, remove suture. The data from the surgeries are reviewed to assess the impact of the antithrombotic drugs.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating.

Where is the study run from?
Policlinico Universitario "Duilio Casula" (Italy)

When is the study starting and how long is it expected to run for?
November 2017 to January 2018

Who is funding the study?
University of Cagliari (Italy)

Who is the main contact?
Dr Enrico Erdas (Scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Enrico Erdas

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11/1968

Study information

Scientific Title
Does antithrombotic prophylaxis worsen early outcome of total thyroidectomy? A retrospective cohort study

Study objectives
It is expected that the incidence of post-operative bleeding and the length of hospital stay after total thyroidectomy would be higher when antithrombotic prophylaxis was administered.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Institutional Ethical Committee University Hospital of Monserrato, University of Cagliari, 20/11 /2017 ref: PROT. PG/2017/8430

Study design
Retrospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please use the contact below to request a patient information sheet erdasenrico@libero.it

Health condition(s) or problem(s) studied
factors influencing outcome of thyroid surgery

Interventions
Participants have antithrombotic prophylaxis with low-molecular-weight heparin (a subcutaneous prophylactic dose (i.e., 0.3 ml) of nadroparin calcium administered the day before their operation and continued for at least 10 days. Participants undergo their thyroid surgery.

After the operation all patients are subject to a close monitoring in the first 12 hours after surgery in order to detect early signs of cervical haematoma, respiratory distress or hypocalcaemia. Drains are removed when the daily amount of fluid collection falls below 20 ml in each reservoir. Parathyroid hormone (PTH) and serum calcium levels are measured on the first and second postoperative day, while further controls are performed only if required (PTH at very low level, clinical signs of hypocalcaemia regardless of serum calcium levels). Post-operative oral calcium and vitamin D supplements are administered in all symptomatic patients with hypocalcemia. After discharge, all patients are re-evaluated within 1 week in order to assess the wound and, if appropriate, remove intradermal suture. All patients underwent telephone follow-up once a week for at least one month.

Researchers review the data about surgical outcomes to investigate the usage of the antithrombotic medication.

Intervention Type
Procedure/Surgery

Primary outcome measure

1. Incidence of severe postoperative cervical hematoma is measured using the the need for surgical revision
2. Length of postoperative hospital stay is measured using patient records at discharge

Secondary outcome measures
Incidence of thromboembolic events is measured using the diagnosis of deep vein thrombosis and/or pulmonary embolism.

Overall study start date
10/11/2017

Completion date
15/01/2018

Eligibility

Key inclusion criteria
All patients submitted to total thyroidectomy for whom antithrombotic prophylaxis would be indicated.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
526 patients

Total final enrolment
526

Key exclusion criteria
1. Aged below 18 years
2. Anticoagulant or antiplatelet therapy
3. Recurrent goitre and operations other than total thyroidectomy (hemithyroidectomy, thyroidectomy with central or lateral neck dissection).

Date of first enrolment
01/02/2013

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
Italy

Study participating centre
Policlinico Universitario "Duilio Casula"
Italy
09042

Sponsor information

Organisation
University of Cagliari

Sponsor details
Via Università, 40
Cagliari
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09124

Sponsor type
University/education

ROR
https://ror.org/003109y17

Funder(s)

Funder type
University/education

Funder Name
University of Cagliari

Results and Publications

Publication and dissemination plan
The study has been completed and will be sent to an international journal by 15/02/2017.

Intention to publish date
15/02/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Enrico Erdas at erdasenrico@libero.it.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/04/2019	13/05/2019	Yes	No