ISRCTN30172374 https://doi.org/10.1186/ISRCTN30172374

The use of a biologic topical haemostatic agent (TachoSil®) for the prevention of postoperative bleeding in patients on antithrombotic therapy undergoing thyroid surgery

Submission date
19/03/2015

Registration date
30/03/2015

Last Edited
04/11/2015

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
An antithrombotic drug is a drug that reduces the formation of blood clots. Patients taking oral antithrombotic drugs are frequently encountered in general surgery. Given the high risk of bleeding during or after the operation, patients may have to temporarily stop taking these drugs. However, bleeding may still occur once they restart taking the drugs. This is especially dangerous in thyroid surgery. Some topical haemostatic drugs have the ability to promote clot formation and may prevent bleeding in patients taking antithrombotic drugs. Among the available products, we decided to test TachoSil®, since it has already proved to be safe and effective in a broad range of surgical procedures. TachoSil is a sponge coated with substances that promote blood clotting. The purpose of this study was to test whether using TachoSil in patients taking antithrombotic drugs could reduce the risk of bleeding after thyroid surgery.

Who can participate?
Patients taking antithrombotic drugs, and scheduled for thyroid surgery.

What does the study involve?
Patients were randomly allocated to be treated with either standard surgical procedures or standard surgical procedures and TachoSil. Over a period of one month after the surgery, we evaluated the occurrence of bleeding, duration of drain use, hospitalization time, and complication rate.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Endocrine Surgery Unit of the University Hospital in Cagliari (Italy).

When is the study starting and how long is it expected to run for?
From November 2011 to May 2014.

Who is funding the study?
University Hospital in Cagliari (Italy).

Who is the main contact?
Assistant Professor Enrico Erdas

Contact information

Type(s)
Scientific

Contact name
Dr Enrico Erdas

ORCID ID
http://orcid.org/0000-0002-7674-9945

Contact details
Via Mameli, 22
Cagliari
Italy
09124

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The use of a biologic topical haemostatic agent (TachoSil®) for the prevention of postoperative bleeding in patients on antithrombotic therapy undergoing thyroid surgery: a randomized controlled trial

Study objectives
The haemostatic agent TachoSil has the ability to promote clot formation when coagulation or platelet functions are impaired. Thus we hypothesized that its use might reduce the incidence of postoperative bleeding in patients on antithrombotic treatment (with impaired coagulation)

Ethics approval required

Old ethics approval format

Ethics approval(s)
Institutional Ethical Committee at University Hospital of Monserrato, University of Cagliari, Italy, 03/12/2011, ref: 354/2011

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Postoperative bleeding after thyroidectomy

Interventions
Group 1: patients undergoing standard surgical hemostasis (FOCUS harmonic scalpel and ligatures)
Group 2: patients for whom a patch coated with human coagulation factors (TachoSil®) was used in addition to standard procedures

Intervention Type
Procedure/Surgery

Primary outcome measure
Post-operative rates of cervical haematoma, that is bleeding requiring wound exploration under general anaesthesia, measured during the first post-operative month

Secondary outcome measures
1. Duration of drain use
2. Postoperative hospitalization time
3. Complication rate
All measured during the first post-operative month.

Overall study start date
13/11/2011

Completion date
28/05/2014

Eligibility

Key inclusion criteria
Patients taking vitamin K antagonists (warfarin or acenocoumarol), or acetyl salicylic acid for the prevention of thromboembolism scheduled for open total thyroidectomy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
70

Key exclusion criteria
Patients treated with antithrombotic drugs other than vitamin K antagonists (warfarin or acenocoumarol), or scheduled for partial thyroidectomy

Date of first enrolment
08/01/2012

Date of final enrolment
28/05/2014

Locations

Countries of recruitment
Italy

Study participating centre
Endocrine Surgery Unit of the University Hospital in Cagliari
SS 554 km 4,500
Monserrato
Italy
-

Sponsor information

Organisation
University of Cagliari

Sponsor details
Via Università, 40
Cagliari
Italy
09124

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/003109y17

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital in Cagliari (Italy)

Results and Publications

Publication and dissemination plan
One article with the main results will be submitted to a peer-reviewed journal

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2015		Yes	No