

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

<b>Submission date</b> 19/03/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/03/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/11/2015	<b>Condition category</b> Surgery	<input type="checkbox"/> 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**  
<https://orcid.org/0000-0002-7674-9945>

**Contact details**  
Via Mameli, 22  
Cagliari  
Italy  
09124

## Additional identifiers

## 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

**Study type(s)**

Prevention

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

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## Sponsor information

**Organisation**

University of Cagliari

**ROR**

<https://ror.org/003109y17>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

University Hospital in Cagliari (Italy)

## Results and Publications

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?
<a href="#">Results article</a>	results	01/08/2015		Yes	No