# 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	Recruitment status No longer recruiting	Prospectively registered		
19/03/2015		Protocol		
Registration date 30/03/2015	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
04/11/2015	Surgerv			

## 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