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Effectiveness of different local haemostatic agents for bleeding control in carotid and femoral artery surgery

Submission date
14/03/2025

Recruitment status
No longer recruiting

Registration date
31/03/2025

Overall study status
Completed

Last Edited
16/06/2025

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A vascular anastomosis is a surgical procedure that is used to connect vessels to each other. The purpose of this study is to evaluate the effectiveness of topical tranexamic acid (TXA) application in reducing bleeding at the site of vascular anastomoses, compared to other local hemostatic agents or the absence of hemostatic treatment.

Who can participate?
Patients aged 18 years and older who underwent carotid endarterectomy or vascular reconstruction of the femoral artery in the groin

What does the study involve?
The study involves dividing patients who undergo carotid endarterectomy and vascular reconstruction of the femoral artery in the groin into three groups. After completion of the anastomosis the first group will locally receive topical tranexamic acid, the second group will receive another standard local haemostatic and the third group will not receive any local haemostatic. A standard Redon drainage will be placed and the content will be measured and recorded.

What are the possible benefits and risks of participating?
All the haemostatic agents used in this study have been previously used in different surgical fields without specific complications. Also, not using local haemostatic agents is a standard procedure in many surgical centres. Therefore, there are no specific benefits and risks for the participants.

Where is the study run from?
University Hospital Centre Zagreb (Croatia)

When is the study starting and how long is it expected to run for?
March 2022 to June 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Andrea Crkvenac Gregorek, acrkvena@kbc-zagreb.hr, andrea.cg72@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
02/013AG

Study information

Scientific Title
Topical application of tranexamic acid on vascular anastomoses - influence on postoperative drainage in comparison with other local haemostatics or no intervention

Study objectives
The topical application of tranexamic acid in vascular surgery is as effective and safe as other standard hemostatic agents, while also being cost-effective.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/05/2023, University Hospital Center Zagreb Ethical Committee (Kispatićeva 12, Zagreb, 10000, Croatia; +385 (0)1 238 88 88; kbc-zagreb@kbc-zagreb.hr), ref: 02/013AG

Primary study design
Interventional

Study design
Prospective randomized double-blind trial

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Reduction of postoperative bleeding from vascular anastomoses after carotid and femoral artery surgery

Interventions
A total of 420 patients (calculated based on power analysis) will be included and divided into two main groups: one undergoing surgical treatment of the carotid artery and the other undergoing surgery on the femoral artery. These two groups represent different anatomical locations, each associated with its own specific complications.

Each group (carotid and femoral) will be further divided into three subgroups of 70 patients. One subgroup will receive TXA, another will receive alternative hemostatic agents, and the third group will serve as a control with no hemostatic agent applied.
Effectiveness will be assessed by measuring the amount of blood drained into a Redon drain 24 hours postoperatively. Treatment will follow standard clinical protocols and professional guidelines. All patients over 18 years of age will provide informed consent prior to participation.

Upon completion of surgical treatment and hemostasis control, and before closure of the surgical wound (i.e., at the point of decision to apply a local hemostatic agent), an envelope containing the details of the hemostatic agent to be applied (TXA, other hemostatics, or no hemostatic) will be opened.

Patients assigned to the TXA group will receive 10 ml of TXA (1000 mg) administered to the vascular anastomosis area in two phases before wound closure. In phase one, 5 ml will be applied to the anastomosis for 10 minutes with gentle compression using damp gauze. In phase two, after placement of the Redon drain and just prior to complete wound closure, the remaining 5 mL (500 mg) of TXA will be applied. The Redon drain will be activated 10 minutes after the final TXA application, ensuring a total duration of TXA application of 20 minutes.

The hemostatic agents used in the second subgroup will include oxidized regenerated cellulose (Fibrillar, Surgicell) or collagen patches coated with physiological coagulation factors (TachoSil), according to the surgeon’s decision.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Effectiveness of haemostasis determined by the amount of blood (in ml) drained into the Redon drain over the course of the first 24 postoperative hours

Key secondary outcome(s)
1. Haematoma formation, assessed clinically from skin closure in the operating theatre to discharge
2. Postoperative wound infection (Surgical Site Infection [SSI]), the presence of infection assessed clinically (examination, wound secretion, temperature measurement, laboratory

parameters, swab for microbiology culture) from the first postoperative day to discharge
3. Lymphorrhea: presence assessed clinically (examination, wound secretion) and by measuring and examining the Redon drainage content from the first postoperative day to discharge

Completion date
01/06/2025

Eligibility

Key inclusion criteria
1. 18 years of age and older
2. Surgical patients who underwent carotid endarterectomy
3. Surgical patients who underwent femoral artery reconstruction in the groin

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
420

Key exclusion criteria
Allergy to tranexamic acid

Date of first enrolment
08/05/2023

Date of final enrolment
07/05/2025

Locations

Countries of recruitment
Croatia

Study participating centre
University Hospital Centre Zagreb
Kišpatićeva 12
Zagreb
Croatia
10000

Sponsor information

Organisation
University Hospital Centre Zagreb

ROR
https://ror.org/00r9vb833

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Andrea Crkvenac Gregorek (acrkvena@kbc-zagreb.hr)

IPD sharing plan summary
Available on request