

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

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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

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Study design

Prospective randomized double-blind trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment, Efficacy

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/03/2022

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

100 Years

Sex

Both

Target number of participants

420

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

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Croatia

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Sponsor information

Organisation

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Sponsor type

Hospital/treatment centre

Website

<https://www.kbc-zagreb.hr/>

ROR

<https://ror.org/00r9vb833>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Intention to publish date

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