

# Novel use of TXA to reduce the need for nasal packing in epistaxis

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<b>Registration date</b> 01/06/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/07/2023	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Nosebleeds are a very common condition. In most cases nosebleeds stop with simple first aid measures, but some cases are more serious, leading to hospital admission or even death. Patients with serious nosebleed attending the emergency department (ED) are initially treated with vasoconstrictors (applying a solution to the inside of the nostril that causes blood vessels to contract) or cauterisation (briefly burning the blood vessel to seal it). If bleeding cannot be stopped with these measures, patients usually undergo nasal packing. Nasal packing involves stuffing the nasal passage tightly with a dressing to apply pressure to the source of the bleeding, which can be an extremely uncomfortable and painful experience. The nasal pack is left in place for about 48 hours and patients are kept in hospital for monitoring during this time. In other conditions where bleeding is a problem, tranexamic acid (TXA) has been shown to help the normal blood clotting process, making clots less likely to break down. TXA has the potential to safely stop serious nosebleeds, and reduce the need for patients to undergo nasal packing and an in-patient hospital stay. The aim of this study is to evaluate the effectiveness of TXA in the treatment of serious nosebleeds.

### Who can participate?

Patients with a serious nosebleed that fails to stop after first aid and initial treatment in the emergency department.

### What does the study involve?

Participants agree to take part while having simple, emergency treatment to for their nosebleed which usually, at least temporarily, controls bleeding. In their nose continues to bleed after the initial treatment, participants continue in the study. These participants are randomly allocated into one of two groups. For those in the first group, a cotton wool roll soaked in TXA is gently inserted into the bleeding nostril and held in place with a nose-clip for about 10 minutes. This can be repeated once more if the bleeding continues. Those in the second group receive the same treatment except the cotton wool roll is soaked in water. Participants in both groups then go on to receive usual care. One week later, participants are contacted by telephone in order to find out about recovery, and medical notes are reviewed.

What are the possible benefits and risks of participating?

TXA may help to stop nose bleeds, so those allocated to receive TXA treatment may benefit from having their nose bleed stop without need for further hospital treatment. There are no notable risks involved with participating.

Where is the study run from?

Royal Devon & Exeter Hospital (lead centre) and 13 other NHS hospitals in England and Scotland (UK)

When is the study starting and how long is it expected to run for?

Study dates as of 19/11/2018:

August 2016 to June 2019

Previous study dates:

August 2016 to January 2019

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr Wendy Ingram

wendy.ingram@plymouth.ac.uk

## Contact information

### Type(s)

Public

### Contact name

Dr Wendy Ingram

### Contact details

Peninsula Clinical Trials Unit

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## Additional identifiers

Clinical Trials Information System (CTIS)

2016-001530-10

Protocol serial number

33607

## Study information

## **Scientific Title**

A randomised controlled trial of topical intranasal tranexamic acid versus placebo to reduce the need for nasal packing in patients presenting to the Emergency Department with spontaneous epistaxis

## **Acronym**

NoPac

## **Study objectives**

The aim of this study is to investigate the safety and efficacy of TXA in stopping serious nosebleeds, reducing the need for patients to undergo nasal packing and an in-patient hospital stay.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

South West - Central Bristol Research Ethics Committee, 03/02/2017, ref: 17/SW/0010

## **Study design**

Randomised; Interventional; Design type: Treatment, Drug

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Epistaxis

## **Interventions**

After written consent has been obtained and eligibility for the study is confirmed, participants will be randomised to receive up to two doses of either topical intranasal TXA or matched placebo. Randomisation will be achieved by means of selection of the next available treatment pack, obtained from a designated, locked cupboard (or other suitable secure location) within the ED at each site. Randomisation packs will be prepared and supplied in advance to participating hospital pharmacy departments by Stockport Pharmaceuticals. Packs will be labelled with a unique number generated by Stockport Pharmaceuticals in conjunction with an independent statistician, using random permuted blocks of variable size to achieve treatment allocation in a 1:1 ratio. Randomisation will be stratified by site. Participants and research staff are blinded to treatment allocation. The trial treatment and comparator will be presented identically.

Intervention group: Participants receive TXA intra-nasally (topically). The dose of TXA is 2ml (200mg) soaked on a dental roll and inserted into the bleeding nostril for 10 minutes. If this does not control the bleeding, then a second dose of 2ml will be given over 10 minutes (400 mg in total). The trial treatment will be prescribed by a clinician who has been approved to undertake this task on the study delegation log.

Control group: Participants receive a placebo intra-nasally (topically). The placebo is 2ml water for injection (for topical use).

In both groups, the treatment will be given in the Emergency Department (ED) during the ED attendance only. No further treatment will be given after discharge or transfer from the ED. The duration of treatment is likely to be around 30 minutes in total (10 mins per dose, plus time to reassess in between doses).

The research nurse will complete data collection up to the time of discharge or transfer from the ED. She will complete follow-up data collection by examination of the participant's ED and hospital records up to one week from the ED admission. One follow-up phone call will be made to the participant 7 days after admission to collect adverse event and outcome data. There will be no further follow-up after one week.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Tranexamic acid

### **Primary outcome(s)**

Use of anterior nasal packing (of any type) for treatment of epistaxis at any time during the ED attendance, as obtained from ED notes.

### **Key secondary outcome(s)**

The following outcomes will be obtained from the ED records, hospital records and at the 7 day follow-up phone call to the participant:

1. Hospital admission
2. Need for blood transfusion
3. Any further treatment for epistaxis during the index ED attendance
4. Recurrent epistaxis requiring hospital treatment, following trial intervention and within 7 days of the index ED attendance
5. Any thrombotic event requiring any hospital re-attendance within 7 days of the index ED attendance
6. Any further hospital treatments required for epistaxis within 7 days of the index ED attendance, including details of the type of hospital episode
7. Number and nature of any adverse events

### **Completion date**

30/06/2019

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18 or over, any gender
2. Presenting to the ED with spontaneous, atraumatic epistaxis, unresolved with simple first aid and standard initial therapy

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

496

**Key exclusion criteria**

1. Clinical evidence of shock, as determined by the treating clinician, or requirement for resuscitation (including but not limited to systolic BP < 90 mmHg).
2. Known allergy to TXA
3. Lacking capacity
4. Unwilling to give consent
5. No telephone or unwilling to be contacted by telephone
6. Known paranasal, nasopharyngeal or nasal cavity malignancy
7. Pregnancy
8. Sent to ED for specialist ENT treatment
9. Already undergone pre-hospital nasal packing
10. Prior participation in the study (i.e. received allocated treatment)
11. Prisoners
12. Epistaxis caused by trauma (excluding simple nose picking)
13. Known haemophilia

**Date of first enrolment**

05/05/2017

**Date of final enrolment**

31/03/2019

**Locations****Countries of recruitment**

United Kingdom

England

Scotland

**Study participating centre**  
**Royal Devon & Exeter Hospital**  
Barrack Road  
Exeter  
United Kingdom  
EX2 5DW

**Study participating centre**  
**Derriford Hospital**  
Derriford Road  
Plymouth  
United Kingdom  
PL6 8DH

**Study participating centre**  
**Royal United Hospital**  
Combe Park  
Bath  
United Kingdom  
BA1 3NG

**Study participating centre**  
**Manchester Royal Infirmary**  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**  
**Gloucester Royal Hospital**  
Great Western Road  
Gloucester  
United Kingdom  
GL1 3NN

**Study participating centre**  
**Cheltenham General Hospital**  
College Road  
Cheltenham  
United Kingdom  
GL53 7AN

**Study participating centre**

**Southmead Hospital**

Southmead Road  
Westbury-on-Trym  
Bristol  
United Kingdom  
BS10 5NB

**Study participating centre**

**North Devon District Hospital**

Raleigh Park  
Barnstaple  
United Kingdom  
EX31 4JB

**Study participating centre**

**Musgrove Park Hospital**

Parkfield Drive  
Taunton  
United Kingdom  
TA1 5DA

**Study participating centre**

**Salford Royal Hospital**

Stott Lane  
Salford  
United Kingdom  
M6 8HD

**Study participating centre**

**Royal Derby Hospital**

51 Little France Crescent  
Edinburgh  
United Kingdom  
EH16 4SA

**Study participating centre**

**Dorset County Hospital**

Williams Avenue  
Dorchester  
United Kingdom  
DT1 2JY

**Study participating centre**

**Royal Cornwall Hospital**

2 Penventinnie Lane  
Treliske  
Truro  
United Kingdom  
TR1 3LQ

**Study participating centre**

**Norfolk and Norwich University Hospital**

Colney Lane  
Norwich  
United Kingdom  
NR4 7UY

**Study participating centre**

**Yeovil District Hospital**

Higher Kingston  
Yeovil  
United Kingdom  
BA21 4AT

**Study participating centre**

**St George's Hospital**

Blackshaw Road  
London  
United Kingdom  
SW17 7EH

**Study participating centre**

**St Thomas' Hospital**

Westminster Bridge Road  
London  
United Kingdom  
SE1 7EH

**Study participating centre**

**John Radcliffe Hospital**

Headley Way  
Headington  
United Kingdom  
OX3 9DU

**Study participating centre**

**Royal London Hospital**

Whitechapel Rd  
London  
United Kingdom  
E1 1BB

**Study participating centre**

**Whipps Cross University Hospital**

Leytonstone  
London  
United Kingdom  
E11 1NR

**Study participating centre**

**Epsom Hospital**

Dorking Road  
Epsom  
United Kingdom  
KT18 7EG

**Study participating centre**

**St Helier Hospital**

Wrythe Lane  
Carshalton  
United Kingdom  
SM5 1AA

**Study participating centre**

**Addenbrookes Hospital**

Hills Road

Cambridge  
United Kingdom  
CB2 0QQ

**Study participating centre**

**Royal Berkshire Hospital**

London Road  
Reading  
United Kingdom  
RG1 5AN

**Study participating centre**

**University Hospitals Coventry and Warwickshire**

Clifford Bridge Road,  
Walsgrave  
Coventry  
United Kingdom  
CV2 2DX

## Sponsor information

**Organisation**

Royal Devon and Exeter NHS Foundation Trust

**ROR**

<https://ror.org/03085z545>

## Funder(s)

**Funder type**

Government

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

IPD sharing statement as of 19/11/2018:

The datasets generated during and/or analysed during the current study will be available upon request from the Sponsor (Royal Devon and Exeter NHS Foundation Trust, email alison.kerridge@nhs.net). The data is likely to be available from January 2020 (after publication of results papers and the final report to the funder). Further information about data sharing will be made available at a later date.

Previous IPD sharing statement:

The current data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/06/2021	06/07/2021	Yes	No
<a href="#">Protocol article</a>	protocol	15/02/2019		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant consent form version 2.0	20/02/2017	11/07/2023	No	Yes