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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
10/04/2017		[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
01/06/2017		[X] Results		
<b>Last Edited</b> 11/07/2023	Condition category Signs and Symptoms	[] 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, empergency 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 N16, ITTC Building 1 Plymouth Science Park Plymouth United Kingdom PL6 8BX +44 1752 315252 wendy.ingram@plymouth.ac.uk

#### Additional identifiers

EudraCT/CTIS number 2016-001530-10

**IRAS** number

ClinicalTrials.gov number

#### Secondary identifying numbers

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

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

See trial outputs table

#### 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 measure

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

#### Secondary outcome measures

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

#### Overall study start date

01/08/2016

#### 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

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

Planned Sample Size: 450; UK Sample Size: 450

#### 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

England

Scotland

**United Kingdom** 

#### 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

#### Sponsor information

#### Organisation

CV2 2DX

Royal Devon and Exeter NHS Foundation Trust

#### Sponsor details

Royal Devon & Exeter Hospital Barrack Road Exeter England United Kingdom EX2 5DW +44 1392 403017 alison.kerridge@nhs.net

#### Sponsor type

Hospital/treatment centre

#### **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**

#### Publication and dissemination plan

The study protocol will be published in an open access clinical journal approximately one year after the recruitment start date. On completion of analyses, a final study report will be prepared for the funder. End of study reports will also be sent to REC and MHRA within 12 months of the end of the study.

The study results will be submitted for publication in international, high impact, peer reviewed journals primarily relating to emergency medicine but also to ENT and primary care specialties.

The CI will draw up a publication policy for the study to outline publication plans and specify how authorship on publications will be determined. Drafts of all papers intended for publication will be sent to the funding body (NIHR RfPB) for review prior to publication and the funding body will be acknowledged within all publications. Members of the TMG, TSC and DMC will also have prior access to the unblinded trial results and embargoed press release(s), subject to suitable confidentiality arrangements. The study findings will be presented at regional, national and international meetings as appropriate.

#### Intention to publish date

31/01/2020

#### 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?
Protocol article	protocol	15/02/2019		Yes	No
Results article		01/06/2021	06/07/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant consent form version 2.0	20/02/2017	11/07/2023	No	Yes