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

Submission date
10/04/2017

Recruitment status
No longer recruiting

Registration date
01/06/2017

Overall study status
Completed

Last Edited
11/07/2023

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
CV2 2DX

Sponsor information

Organisation
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