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Topical tranexamic acid in total hip replacement

Submission date
05/02/2012

Recruitment status
No longer recruiting

Registration date
24/04/2012

Overall study status
Completed

Last Edited
28/08/2015

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
A total hip replacement (THR) is a common type of surgery where a damaged hip joint is replaced with an artificial one. Losing blood is common after THR and a blood transfusion may be required. Although safer than ever, blood transfusion still carries risks, so we need to find new ways to reduce blood loss and blood transfusion. Tranexamic acid is a drug used to stop bleeding. It has been successfully used to stop bleeding after dental operations, removal of tonsils, prostate surgery and heavy menstrual bleeding. It works by preventing the blood clot from dissolving. There is increasing evidence that tranexamic acid can reduce blood loss and the need for blood transfusion significantly after intravenous use (injecting into a vein) in THR patients. It is thought that topical application (applying tranexamic acid directly to the wound) may have a bigger effect at reducing blood loss and even fewer side effects; however, this remains to be demonstrated by this study. This study is designed to find out if tranexamic acid can reduce blood loss and the need for blood transfusion in patients undergoing THR.

Who can participate?
Patients undergoing a primary (first) THR.

What does the study involve?
Participants are randomly allocated to one of two groups: one group receives tranexamic acid and a second group receives a placebo (a dummy solution which looks like tranexamic acid but contains no active ingredient). The operation is conducted in the standard way and the only difference is squirting the TXA into the wound at the end of the operation and before the wound is closed. We will measure the differences in blood loss and blood transfusion, length of stay, hip function, quality of life and number of complications between the two groups.

What are the possible benefits and risks of participating?
The following side effects have been reported with the use of tranexamic acid: nausea, vomiting, diarrhoea and disturbance in colour vision. These are usually temporary and much less likely to happen after one dose applied directly into the wound. There is a theoretical increased risk in developing deep vein thrombosis and pulmonary embolism. However, some similar studies to this one where tranexamic acid was injected into a vein, have not found an increase in this risk. Moreover, one study showed that applying tranexamic acid directly to the wound does not lead to absorption into the blood, minimising the side effects.

Where is the study run from?
The North Tees and Hartlepool University Hospital (UK).

When is study starting and how long is it expected to run for?
August 2009 to October 2010.

Who is funding the study?
The North Tees and Hartlepool University Hospital (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2009-012141-34

Protocol serial number
TRANX-H version 2-19/2/2009

Study information

Scientific Title
Topical (intra-articular) tranexamic acid reduces blood loss and transfusion rates following total hip replacement: a randomised controlled trial (TRANX-H)

Acronym
TRANX-H

Study objectives

We hypothesised that topical tranexamic acid (TXA) would provide a high concentration at the bleeding site, effectively limiting blood loss, with little or no systemic side effects following total hip replacement (THR).

Thus, we investigated the use of TXA sprayed topically into the exposed tissue around the hip joint prior to the wound closure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newcastle & North Tyneside 1 Research Ethics Committee, June 2009, ref: 09/H0906/62

Study design
Double-blind placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Joint arthritis

Interventions
Randomisation was web-based and provided by a commercial provider (Sealed Envelope). The site was accessed by designated, named theatre staff only, each issued with a user name, password and pin number. When a consented patient arrived at theatre, the designated theatre staff accessed the randomisation web site. Anonymous basic details of the patients and surgeon were entered (to allow stratification and subsequent identification) and staff confirmed details before randomisation. Subsequently a unique identifier number and allocation group was provided. These staff prepared the study medicine and provided it to the surgeons. Surgeons and their team members and patients remained blinded to the allocation. Outcomes measures were either objective data (blood transfusion, HB, Hct level, length of stay) or patient self-reported questionnaires. Follow up was for 3 months.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Blood transfusion rate
2. Number of blood units transfused until discharge

Key secondary outcome(s))
1. The visible drain blood loss (first 48 hours)
2. Haemoglobin and Haematocrit drops (on day 2 postoperatively)
3. General quality of life measure (EUROQOL) preoperative and at 3 months postoperative
4. Oxford hip score preoperative and at 3 months postoperative
5. Length of stay
6. Cost effectiveness analysis

Completion date
15/10/2010

Eligibility

Key inclusion criteria
Patients undergoing a primary THR

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Allergic to TXA
2. Warfarin or heparin, had a history of haemophilia
3. Deep venous thrombosis, pulmonary embolism
4. Renal impairment
5. Female patients were excluded if they were pregnant

Date of first enrolment
15/08/2009

Date of final enrolment
15/10/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The North Tees and Hartlepool University Hospital
Stockton-on-Tees
United Kingdom
TS19 8PE

Sponsor information

Organisation
University Hospital of North Tees and Hartlepool (UK)

ROR
https://ror.org/04zzrht05

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of North Tees and Hartlepool (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/11/2013		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes