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Use of tranexamic acid for the prevention of blood loss in cesarean delivery: the EPTAC trial

Submission date
15/03/2019

Recruitment status
No longer recruiting

Registration date
04/04/2019

Overall study status
Completed

Last Edited
28/12/2022

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Minimizing blood loss during delivery whether vaginal or abdominal is an important preventive health objective aimed at reducing related morbidities and mortality for which various interventions have been used to achieve this purpose however postpartum haemorrhage remains a major cause of maternal mortality especially in developing countries. The aim of this study is to determine the effect of tranexamic acid on blood loss at Caesarean section.

Who can participate?
All pregnant women scheduled for a primary (singleton pregnancy) can participate.

What does the study involve?
Before undergoing Caesarean section participants will be assigned to either receive an injection of tranexamic acid or placebo. The research participant, the individual(s) who administer the treatment, and the individual(s) who assess the outcomes will not know which treatment has been provided in order to make the study more accurate. During and after the procedure blood loss will be measured to assess which treatment is associated with less blood loss.

What are the possible benefits and risks of participating?
Participants' blood level (PCV) will be checked at no cost before and after the procedure with closer monitoring of the participants and their babies before, during and after the procedure. You would be contributing to knowledge and helping us know how to further reduce bleeding in our women having caesarean delivery. Not all participants will receive tranexamic acid. Assuming you do, common side effects include headaches however you will be on pain relief that will take care of this. Tranexamic acid is a category B drug which means animal studies have shown it is safe for the baby. This is not demonstrated in humans, though it is in the same group as heparin and common antibiotics used in pregnancy. Thromboembolic effects of tranexamic acid were only demonstrated at high recurrent doses which is higher than a single 1 g dose you will be receiving during the study and those already with this risk will be excluded from the study.

Where is the study run from?
Irrua Specialist Teaching Hospital, Benin Auchi Expressway, Irrua, Edo State, Nigeria.

When is the study starting and how long is it expected to run for?
April 2019 to January 2020

Who is funding the study?
Irrua Specialist Teaching Hospital, Nigeria

Who is the main contact?
Dr. Olorungbogo Olugbenga, olorung@gmail.com

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
00001

Study information

Scientific Title
Efficacy of preoperative Tranexamic acid in reducing blood at Caesarean section; a randomized controlled trial at Irrua, Edo state.

Acronym
EPTAC

Study objectives
Preoperative tranexamic acid reduces blood loss at Caesarean section.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/01/2019, Ambrose Alli University, Ekpoma Health Research Ethics Committee (Irrua, Edo state, Nigeria; cle21200@gmail.com; +2347058777005), ref: NHREC/12/06/2013. In collaboration with Irrua Specialist Teaching Hospital Research and Ethics Committee (Irrua, Edo State, Nigeria; isth.rec.2015@gmail.com)

Study design
Triple blind randomized placebo controlled trial.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obstetric haemorrhage

Interventions
Preoperative intravenous tranexamic acid 1g(10mls) vs Preoperative intravenous water for injection (10mls) as placebo.
Randomization into groups is by simple balloting, drawing numbers from a ballot box.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Tranexamic Acid

Primary outcome(s)
Blood loss at Caesarean section and within 24 hours after surgery using galvametric and volumetric approach of estimation.

Key secondary outcome(s))
1. The difference in 1hr preoperative packed cell volume and 48hrs postoperative packed cell volume.
2. Additional oxytocic requirement, blood transfusion, caesarean hysterectomy or maternal death as a result of primary Post Partum Haemorrhage.
3. APGAR scores in first and fifth minutes and Neonatal Intensive care unit admissions/outcome.
4. Maternal satisfaction prior to discharge measured using a scale of 0-10; Where 0- extreme dissatisfaction and 10-ultimate satisfaction

Completion date
24/01/2020

Eligibility

Key inclusion criteria
1. All pregnant women scheduled for a primary Caesarean section
2. Singleton pregnancy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
208

Key exclusion criteria
1. Multiple gestation
2. Any other additional risk of bleeding apart from the Caesarean section such as previous caesarean section, antepartum haemorrhage, polyhydramnios and bleeding disorders.
3. Liver or Renal pathologies
4. Patients who chose not to participate in the study.
5. Allergy to Tranexamic acid
6. Women unfit to give an informed consent e.g. the eclamptic, unconscious or those with mental impairment.

Date of first enrolment
01/04/2019

Date of final enrolment
24/01/2020

Locations

Countries of recruitment
Nigeria

Study participating centre
Irrua Specialist Teaching Hospital
Benin Auchi Expressway
Irrua
Nigeria
310112

Sponsor information

Organisation
Irrua Specialist Teaching Hospital

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Irrua Specialist Teaching Hospital (Nigeria)

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2021	28/12/2022	Yes	No