**WHO Trial Registration Data Set**

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| 1 | Primary Registry and Trial Identifying Number | NCT04274335 |
| 2 | Date of Registration in Primary Registry | 18 February 2020 |
| 3 | Secondary Identifying Numbers | Sponsor ref: LSHTM 2020-KEP-401LSHTM Ethics ref: 21255 |
| 4 | Source(s) of Monetary or Material Support | WellcomeBill & Melinda Gates Foundation |
| 5 | Primary Sponsor | London School of Hygiene & Tropical Medicine |
| 6 | Secondary Sponsor(s) | n/a |
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| 8 | Contact for Scientific Queries | Haleema Shakur-Still, Clinical Trials Unit, Keppel Street, London, WC1E 7HT, UK+44 (0)20 7299 4684 Womanptxa@Lshtm.ac.uk |
| 9 | Public Title | Pharmacokinetics and pharmacodynamics of tranexamic acid in women having caesarean section birth (WOMAN-PharmacoTXA) |
| 10 | Scientific Title | A randomised controlled trial to assess the pharmacokinetics and pharmacodynamics of intramuscular, intravenous and oral administration of tranexamic acid in women giving birth by caesarean section |
| 11 | Countries of Recruitment | Zambia and Pakistan |
| 12 | Health Condition(s) or Problem(s) Studied | Postpartum haemorrhage |
| 13 | Intervention(s) | Active Comparator: Tranexamic acid (TXA) intravenous, intramuscular and oral liquid. Control intervention: No treatment.Women will be randomised to one of the following groups:1. 1 gram dose of TXA by IV injection about 1 hour before CS. Number of participants = 302. 1 gram dose of TXA by IM injection about 1 hour before CS. Number of participants =303. 4 g of TXA solution orally about 1 h before CS. Number of participants = 304. No administration of TXA. Number of participants = 30 |
| 14 | Key Inclusion and Exclusion Criteria | Inclusion Criteria:* Women admitted to hospital giving birth by CS
* History of at least one risk factor for PPH
* Adult (≥18 years old)

Exclusion Criteria: * Women giving birth vaginally
* Women with a known allergy to TXA or its excipients
* Women with current antepartum haemorrhage
* Women known to have received TXA within 48 hours prior to randomisation
* Women with known renal impairment
* Women with any known blood clotting disorder
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| 15 | Study Type | Type of study: interventionalMethod of allocation: randomisedMasking: None (Open Label)Assignment: parallel, 4 armsPhase: 2Enrolled participants will be randomised into one of the four groups described in section 13. The allocation sequence for each dosing cohort will be created using computer-generated random numbers, using blocking to ensure the required balance in the allocation of participants to treatment arms. The allocation ratio will be 1:1:1:1  |
| 16 | Date of First Enrolment | 18 December 2020 |
| 17 | Sample Size | Planned sample size: 120 |
| 18 | Recruitment Status | Recruiting |
| 19 | Primary Outcome(s) | Blood TXA over time up to 24 hours after randomisation |
| 20 | Key Secondary Outcomes | Concentrations of TXA in cord blood after birth and neonate level within the first 24 hours of birthBlood D-dimer concentrations over time up to 24 hours after randomisationVolume of blood lost from incision to 2 hours from CSLocal reactions at injection site and adverse events up to 7 daysNeonate status Apgar scoreClinical diagnosis of PPH up to 24 hours after birth (total blood loss of >1000 mL or any blood loss sufficient to cause haemodynamic instability or requires treatment) |
| 21 | Ethics Review | Status: ApprovedDate of approval: 17 April 2020Name and contact details of Ethics committee(s): Professor Jimmy Whitworth (Chair), Observational / Interventions Research Ethics Committee, London School of Hygiene & Tropical Medicine, Keppel St, London EC1E 7HT. ethics@lshtm.ac.ukIn addition, Ethics Committee (EC) and Regulatory Agencies approvals are in place at national level and at each participating site in Pakistan and Zambia. The approvals are included as part of our submission. The Committees and regulatory Authorities that have approved the trial are:University of Zambia Biomedical Research Ethics Committee (UNZABREC, Ref: 933-2020), Zambia Medicines Regulatory Authority (ZAMRA, Reference: DMS/7/9/22/CT/102), Zambia National Health Research Authority (NHREB), National Bioethics Committee Pakistan (NBC, Ref:4-87/NBC-532/20/409), the Drug Regulatory Authority of Pakistan [DRAP, Reference: F. No. 16-16/2020 DD (PS)], the Ethical Review Board of MCH Centre-Pakistan Institute of Medical Sciences Hospital (Reference: F1-1/2015/ERB/SZABMU/583) and the Ethics Committee of the Federal Government Polyclinic Hospital (Reference: FGPC.1/12/2020/Ethical Committee). |
| 22 | Completion date | 1 May 2021, or when 120 evaluable participants have been recruited. |
| 23 | Summary Results | n/a – trial in progress |
| 24 | IPD sharing statement | Plan to share IPD: YesPlan description: The LSHTM CTU is committed to sharing its clinical study data for additional, ethical research with justified scientific objectives. Until all planned analyses are completed by the LSHTM CTU, data will be shared through a controlled access approach whereby researchers can make formal applications for data sharing. Afterwards, totally anonymised data will be shared via the LSHTM CTU data sharing platform at freebird.lshtm.ac.uk. |