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Tranexamic acid for anaemia trial

Submission date
26/11/2025

Recruitment status
Not yet recruiting

Registration date
04/12/2025

Overall study status
Ongoing

Last Edited
04/12/2025

Condition category
Haematological Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Anaemia (also known as low blood) is when the body does not have enough healthy red blood cells to carry oxygen. It is very common in women, especially young women, because they lose blood every month during their periods.
Anaemia can make women feel tired, weak, dizzy and out of breath. It can make it harder for them to study, work or look after their family. If women become pregnant with anaemia, it can cause problems for them and their baby, such as early birth or heavy bleeding when giving birth.
Half a billion women in the world have anaemia but current treatments are not enough. Iron and vitamins help, but they do not always work well on their own, especially for women who lose a lot of blood every month.
We want to find better ways to treat anaemia. A medicine called tranexamic acid (TXA) helps reduce bleeding by helping blood clot better. It is already used for heavy periods in some countries, but we don't know if it works well when used with iron and vitamins for women with anaemia.
This study aims to find out if giving TXA to women during their period, in addition to standard iron and folic acid supplements, helps to cure anaemia better than supplements alone.

Who can participate?
We are inviting women aged 18 years and older who:
1. Have anaemia (low blood), we will provide a free test to check for anaemia
2. Have periods
3. Are not pregnant and don't plan to get pregnant during the trial

What does the study involve?
Participants will take tablets three times a day during their period for up to 5 days, for 6 periods in a row (about 6 months).
Participants will receive the standard treatment for anaemia: daily iron and folic acid tablets for 3 months.
Participants will be randomly divided into two groups. One group will receive TXA tablets, and the other will receive placebo tablets. The placebo tablets look the same but have no active medicine.
Participants will keep a diary of their symptoms and attend follow-up visits to have their blood pressure, heart rate, and haemoglobin levels checked.
A subgroup of about 300 participants will be asked to provide additional blood, urine, and stool

samples to check for conditions like vitamin deficiencies, sickle cell disease, schistosomiasis, and intestinal parasites, helping researchers understand the main causes of anaemia.

What are the possible benefits and risks of participating?
By taking part, participants will help find better ways to treat anaemia for women everywhere. They may also get free supplementation, health checks, and advice during the trial. TXA is widely used and safe (for instance, it is recommended in many countries as a treatment for heavy menstrual bleeding). However, rare side effects can include nausea or diarrhoea. There is a theoretical risk of blood clots, but previous large studies have not shown an increase in this risk with TXA.

Where is the study run from?
The study is coordinated by the London School of Hygiene & Tropical Medicine (UK) and takes place in hospitals, universities, and community settings in Nigeria, Pakistan, and Tanzania.

When is the study starting and how long is it expected to run for?
February 2026 to September 2028

Who is funding the study?
1. Open Philanthropy Project (USA)
2. Jon Moulton Charity Trust (UK)

Who is the main contact?
Eni Balogun, woman3@lshtm.ac.uk

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT06519422

Study information

Scientific Title
The effects of tranexamic acid on anaemia, menstrual health and the wellbeing of women: an international randomised, placebo-controlled trial among menstruating women with anaemia

Acronym
WOMAN-3

Study objectives
Primary objective:
To determine the effect of giving oral TXA during menstruation in adult women for the treatment of anaemia.

Secondary objectives:
We will also assess the effects of TXA on serum ferritin (a key secondary outcome); participant reported menstrual health and blood loss, wellbeing; adverse effects and treatment adherence.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 22/10/2025, London School of Hygiene and Tropical Medicine Observational and Interventions Research Ethics Committee (Keppel Street, London, WC1E 7HT, United Kingdom; +44 (0)20 7636 8636; ethics@lshtm.ac.uk), ref: 31315

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Anaemia

Interventions
Participants are randomised using blocked randomisation to:

Experimental:
Tranexamic acid (TXA) 1 g (two 500 mg tablets) orally, three times daily, from the first to the last day of menstruation for up to 5 days, during 6 successive menstrual periods.

Placebo:
Matched placebo tablets orally, three times daily, from the first to the last day of menstruation for up to 5 days, during 6 successive menstrual periods

Intervention Type
Drug

Phase
Phase III

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

Primary outcome(s)
1. Proportion of participants with anaemia at the end of the intervention period measured using venous blood samples at baseline and at the end of the intervention period - after the 6th

menstrual period but before the 7th, or within 9 months from randomisation, whichever occurs first.

Key secondary outcome(s))

1. Haemoglobin (Hb) concentration measured using venous blood samples at baseline and at the end of the intervention period - after the 6th menstrual period but before the 7th, or within 9 months from randomization, whichever occurs first.

2. Severity of anaemia measured using Hb in venous blood (mild anaemia (Hb=110-119 g/L); moderate anaemia (Hb=80-109 g/L); severe anaemia (Hb < 80 g/L) at baseline and at the end of the intervention period - after the 6th menstrual period but before the 7th, or within 9 months from randomization, whichever occurs first.

3. Serum ferritin measured using venous blood sample and CRP-adjusted ferritin (see below, under C-reactive protein) at baseline and at the end of the intervention period - after the 6th menstrual period but before the 7th, or within 9 months from randomization, whichever occurs first.

4. Iron deficiency defined as ferritin <15 ug/L (WHO definition) and defined as ferritin <30 ug/L, (new clinical consensus) measured using serum ferritin from venous blood samples with CRP-adjusted ferritin at baseline and at the end of the intervention period - after the 6th menstrual period but before the 7th, or within 9 months from randomization, whichever occurs first.

5. C-reactive protein (CRP) measured using venous blood samples analyzed by immunoassay methods to adjust ferritin values, as detailed in the Statistical Analysis Plan (SAP), because normal ferritin concentrations may mask iron deficiency in the presence of inflammation, at baseline and at the end of the intervention period - after the 6th menstrual period but before the 7th, or within 9 months from randomization, whichever occurs first.

6. The proportion of participants with iron-deficiency anaemia, defined as presence of both anaemia (Hb<120 g/L) plus iron deficiency (ferritin <15 ug/L AND/OR <30 ug/L) measured using venous blood samples at baseline and at the end of the intervention period - after the 6th menstrual period but before the 7th, or within 9 months from randomization, whichever occurs first.

7. Menstrual blood loss measured using self-reported number of menstrual products used at first menstrual period through to the final visit which will take place after the 6th menstrual period or within 9 months from randomization

8. Perceived change in menstrual blood loss measured using visual analogue scales (HMBVAS) and participants' subjective assessment of intensity and impact of menstrual bleeding, at baseline and during in-person follow-up visits and at the final visit (after 6th menstrual period or within 9 months from randomization).]

9. Degree of impact of menstrual bleeding on health-related quality of life measured using the SAMANTA scale at baseline and during in-person follow-up visits and the final visit (after 6th menstrual period or within 9 months from randomization).

10. Menstrual cycle characteristics measured using assessment of cycle frequency, duration, regularity, flow volume, and period pain severity at baseline and throughout the trial up to the final visit (after 6th menstrual period or within 9 months from randomization)

11. Haemoglobin, serum ferritin, and vital signs measured using HemoCue® fingerprick tests and a blood pressure monitor at each scheduled visit during six menstrual cycles and at the final visit, after the 6th menstrual period or within 9 months of randomization. Haemoglobin and serum ferritin will also be analysed from venous blood samples at the final visit.

12. Cost-effectiveness analysis measured using an evaluation of costs and health outcomes as specified in the Statistical Analysis Plan at study completion

13. Participant satisfaction measured using an assessment of participant satisfaction with trial treatment at final visit - after 6th menstrual period or within 9 months from randomization

14. Treatment side effects and adherence measured using data collected on side effects of trial treatment and assessment of adherence at each follow up visit/call during six menstrual cycles and at the final visit, after the 6th menstrual period or within 9 months of randomization. Adherence will be assessed through participant diaries, tablet counts, and Mitra® micro-sampling for TXA levels in a subset of participants.

15. Participant feedback measured using collection of open-ended feedback on trial experiences at all timepoints throughout the trial from enrollment through the final visit after the 6th menstrual period or within 9 months of randomization.

16. Overall wellbeing and fatigue measured using the FACIT-fatigue subscale questionnaire at baseline and during in-person follow up visits and the final visit (after the 6th menstrual period or within 9 months from randomization).

17. Time from randomisation to resolution of anaemia, defined as Hb >12 g/dL (or 120 g/L) measured using venous blood samples (full blood count) at baseline and HemoCue® measurements at each in-person visit, with final assessment after the 6th menstrual period or within 9 months of randomisation

Completion date
30/09/2028

Eligibility

Key inclusion criteria
1. Adult women aged 18 years and older.
2. Currently menstruating, with menstrual periods occurring at least every 38 days and lasting ≥2 days.
3. Anaemia at screening, defined as hemoglobin (Hb) <120 g/L by point-of-care finger prick test.
4. Willing and able to provide informed consent.
5. Able to attend in-person follow-up visits during the trial period.

Individuals with known thalassaemia and sickle cell disease are eligible to participate and take the trial treatment but will not be given standard of care iron supplementation unless it is prescribed by their own treating clinician. They will continue to receive their usual standard care.

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 years

Upper age limit
70 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Planning to get pregnant during the trial period
2. Already taking TXA
3. Known to have possible contraindications to TXA treatment (including allergy to TXA or its excipients, renal impairment, active thromboembolic disease, history of venous or arterial thrombosis, history of convulsion)

Date of first enrolment
28/02/2026

Date of final enrolment
30/03/2028

Locations

Countries of recruitment
Nigeria

Pakistan

Tanzania

Study participating centre
University of Dar es Salaam Mlimani Campus
Dar es Salaam
Tanzania

Study participating centre
Mbeya College of Health and Allied Sciences UDSM MCHAS
Mbeya
Tanzania

Study participating centre
University College Hospital
Queen Elizabeth Road
Ibadan
Nigeria

Study participating centre
Oyo State College of Nursing and Midwifery
Ibadan
Nigeria

Study participating centre
Allama Iqbal Medical College
Lahore
Pakistan

Study participating centre
Ayub Medical Teaching Institution
Abbottabad
Pakistan

Study participating centre
Jinnah Postgraduate Medical Centre
Karachi
Pakistan

Study participating centre
King Edward Medical University
Lahore
Pakistan

Study participating centre
Rawal Institute of Health Sciences
Islamabad
Pakistan

Study participating centre
Shifa Tameer e Millat University
Islamabad
Pakistan

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type

Funder Name
Open Philanthropy Project

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
Jon Moulton Charity Trust

Alternative Name(s)
The Jon Moulton Charity Trust

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
We are committed to sharing data for ethical research with justified scientific objectives. Until all planned analyses are completed by the LSHTM CTU Global Health Trials Group, data will be shared through a controlled access approach; thereby researchers can make formal applications for data sharing. Afterwards, we will share the anonymised dataset via the LSHTM CTU Global Health Trials Group data sharing platform at https://freebird.lshtm.ac.uk/ or a similar platform.

IPD sharing plan summary
Available on request, Stored in publicly available repository