WOMAN3

Tranexamic acid for anaemia treatment trial

Participant's Diary and Information Booklet

COUNTRY	
SITE NAME	
SITE ID	
PARTICIPANT ID NUMBER	
RANDOMISATION NUMBER	

All your answers will remain strictly confidential.

- **Please complete this diary throughout the trial.**
- **Keep this booklet in a safe place.**
- **Keep it with a pen in a place where you will remember to complete it.**
- **<u>Please bring this booklet with you to every study visit.</u>**

Please try your best to take the study tablets as instructed and record any issues you may encounter.
With every diary entry you complete you increase the quality of our research.

We are grateful for your time and effort!

If you have any questions or need any help in answering the questions, please contact us (see contact information below).

Contact Information

To contact the research team for any reason:

Contents of this booklet

SECTION 1: YOUR DAILY DIARY

A HOW TO COMPLETE YOUR DAILY DIARY

- Start filling out your **Daily Diary** on the start date shown on each diary sheet.
- This will be about one or two days before your menstrual period is expected to start.
- Complete the diary each day until your menstrual period ends.
- Circle all the statements that apply to how you feel each day; you may circle more than one statement.
- Indicate if your period has started and you are menstruating – if **yes**, also complete the remaining columns:

- Take your study medication during each of your next six menstrual periods.
  Take **2 tablets** at a time unless advised otherwise by the study team or your healthcare provider.
- Take your first 2 tablets as soon as your menstrual period starts.
- In the diary, indicate the number of tablets taken on the relevant day and time:

 = morning after getting up

 = during the day, e.g. in the afternoon

 = at night before going to sleep

Additional Medication for Menstrual Pain

- Record if you have taken any additional medication each day specifically for menstrual pain.
- If yes, record the details of the medication taken on second page of your diary – provide the name, dose and frequency of the medication taken.
  For example, *Ibuprofen 200mg, 1 tablet, 2 times a day*.

Issues/Comments/Other Medication

- If you experience any other issues or have comments whilst completing your daily diary that you wish to report, you may record this on the second page.
- For any other medications taken (for reasons other than menstrual pain), also record these on the second page of the diary.

- Complete the diary each day until your menstrual period ends – you should complete one row per day. If your bleeding lasts more than ten days, let the study team know.
- You may use the 'date' column to record the calendar date to help keep track, if this helps you.

EXAMPLE – Completed Daily Diary

Section B – Daily Diary Page 1

B. YOUR DAILY DIARY

1st MENSTRUAL CYCLE

Start date of diary (Day 1): 5th /April 2025 (DD MM YYYY) Start time *(approx.)*: 10 00 (Use 24-hr clock; HH MM) Day of the week: Saturday (Mon/Tue/Wed/Thu/Fri/Sat/Sun)

DATE	DIARY DAY	'I feel well today' – Considering all physical, mental and social aspects, circle one per row below to **which best indicates overall how well you feel today:**					Are you menstruating today? *(circle)* IF YES, PLEASE COMPLETE COLUMNS TO RIGHT →		MENSTRUAL PERIOD: STUDY TABLETS (TXA/Placebo) For each day/time of your period put number of tablets (e.g. "2") *[max. 5 days or 5x6=30 tablets]*			Total number of menstrual products used today i.e. bedtime to bedtime? [Enter number]	What was the worst menstrual pain that you experienced today on a scale of 0-10? [Enter number] 0 = no pain, 10 = worst imaginable pain.	Any additional medication taken for menstrual pain? (tick ✓). If **yes**, record details on next page
									⛅	☀	🌙			
05/04	1.	NOT AT ALL	A LITTLE BIT	(SOMEWHAT)	QUITE A BIT	VERY MUCH	YES	NO						
06/04	2.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	(QUITE A BIT)	VERY MUCH	YES	NO	–	2	2	6	5	✓
07/04	3.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	(QUITE A BIT)	VERY MUCH	YES	NO	2	2	2	7	3	-
08/04	4.	NOT AT ALL	A LITTLE BIT	(SOMEWHAT)	QUITE A BIT	VERY MUCH	YES	NO	2	2	2	5	2	-
09/04	5.	NOT AT ALL	(A LITTLE BIT)	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO	2	2	–	4	1	-
10/04	6.	NOT AT ALL	(A LITTLE BIT)	SOMEWHAT	QUITE A BIT	VERY MUCH	YES							
	7.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES							
	8.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES							
	9.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES							
	10.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES							

Section C – Daily Diary Page 2

C. YOUR DAILY DIARY (CONTINUED)

1st MENSTRUAL CYCLE

Further details regarding daily medication or other comments/observations:

Day	Additional medication taken on this day for menstrual pain – details: *Record name, dose and frequency of medication taken each day. E.g. Ibruprofen 200mg, 1 tablet, 2 times a day.*	Any other medicines used, comments or issues to report (for this menstrual period): *For other medications: Record name, dose and frequency of medication taken each day and reason. E.g. Amoxicillin 250mg, 1 tablet, 3 times a day for a chest infection.*
1	-	-
2	Paracetamol, 500mg, 4 tablets	None
3		
4		

B **YOUR DAILY DIARY**

PARTICIPANT ID NUMBER		SITE ID		DATE OF TRIAL ENROLMENT	

1st Menstrual Cycle

Start date of diary (Day 1):____ / ____ / _____ **Start time** *(approx):* ____ : ____ **Day of the week:** _____

DD MM YYYY Use 24-hr clock HH MM Mon/Tue/Wed/Thu/Fri/Sat/Sun

DATE	DIARY DAY	'I feel well today' Considering all physical, mental and social aspects, circle One per row below to **which best indicates overall how well you feel today**:					Are you menstruating today? *(circle)* IF YES, PLEASE COMPLETE COLUMNS TO RIGHT ➔		MENSTRUAL PERIOD					
									STUDY TABLETS (TXA/Placebo) For each day/time of your period put number of tablets (e.g. "2") *[max. 5 days or 5x6=30 tablets]*			Total number of menstrual products used today i.e. bedtime to bedtime? [Enter number]	What was the worst menstrual pain that you experienced today on a scale of 0-10? [Enter number] 0 = no pain, 10 = worst imaginable pain	Any additional medication taken for menstrual pain? (tick ✓). If **yes**, record details on next page
														
	1.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	2.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	3.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	4.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	5.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	6.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	7.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	8.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	9.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	10.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						

C YOUR DAILY DIARY (Continued)

PARTICIPANT ID NUMBER

SITE ID

1st Menstrual Cycle

Further details regarding daily medication or other comments/observations:

Day	Additional medication taken on this day for menstrual pain – details: *Record name, dose and frequency of medication taken each day. E.g. Ibuprofen 200mg, 1 tablet, 2 times a day.*	Any other medicines used, comments or issues to report (for this menstrual period): *For other medications: Record name, dose and frequency of medication taken each day and reason. E.g. Amoxicillin 250mg, 1 tablet, 3 times a day for a chest infection.*
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B YOUR DAILY DIARY

PARTICIPANT ID NUMBER | SITE ID | DATE OF TRIAL ENROLMENT

2nd Menstrual Cycle

Start date of diary (Day 1):_____ / _____ / _____ **Start time** *(approx)*: _____ : _____ **Day of the week:** _____

DD MM YYYY Use 24-hr clock HH MM Mon/Tue/Wed/Thu/Fri/Sat/Sun

DATE	DIARY DAY	'I feel well today' Considering all physical, mental and social aspects, circle One per row below to **which best indicates overall how well you feel today**:					Are you menstruating today? *(circle)* IF YES, PLEASE COMPLETE COLUMNS TO RIGHT ➔		MENSTRUAL PERIOD					
									STUDY TABLETS (TXA/Placebo) For each day/time of your period put number of tablets (e.g. "2") *[max. 5 days or 5x6=30 tablets]*			Total number of menstrual products used today i.e. bedtime to bedtime? [Enter number]	What was the worst menstrual pain that you experienced today on a scale of 0-10? [Enter number] 0 = no pain, 10 = worst imaginable pain	Any additional medication taken for menstrual pain? (tick ✓). If **yes**, record details on next page
														
	1.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	2.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	3.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	4.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	5.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	6.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	7.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	8.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	9.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	10.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						

C YOUR DAILY DIARY (Continued)

PARTICIPANT ID NUMBER

SITE ID

2nd Menstrual Cycle

Further details regarding daily medication or other comments/observations:

Day	Additional medication taken on this day for menstrual pain – details: *Record name, dose and frequency of medication taken each day. E.g. Ibuprofen 200mg, 1 tablet, 2 times a day.*	Any other medicines used, comments or issues to report (for this menstrual period): *For other medications: Record name, dose and frequency of medication taken each day and reason. E.g. Amoxicillin 250mg, 1 tablet, 3 times a day for a chest infection.*
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B **YOUR DAILY DIARY**

PARTICIPANT ID NUMBER		SITE ID		DATE OF TRIAL ENROLMENT	

3rd Menstrual Cycle

Start date of diary (Day 1):_____ / _____ / _____ **Start time** *(approx):* _____ : _____ **Day of the week:** _____

DD MM YYYY Use 24-hr clock HH MM Mon/Tue/Wed/Thu/Fri/Sat/Sun

DATE	DIARY DAY	'I feel well today' Considering all physical, mental and social aspects, circle One per row below to **which best indicates overall how well you feel today**:					Are you menstruating today? *(circle)* IF YES, PLEASE COMPLETE COLUMNS TO RIGHT ➔		MENSTRUAL PERIOD					
									STUDY TABLETS (TXA/Placebo) For each day/time of your period put number of tablets (e.g. "2") *[max. 5 days or 5x6=30 tablets]*			Total number of menstrual products used today i.e. bedtime to bedtime? [Enter number]	What was the worst menstrual pain that you experienced today on a scale of 0-10? [Enter number] 0 = no pain, 10 = worst imaginable pain	Any additional medication taken for menstrual pain? (tick ✓). If **yes**, record details on next page
														
	1.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	2.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	3.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	4.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	5.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	6.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	7.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	8.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	9.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	10.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						

C YOUR DAILY DIARY (Continued)

PARTICIPANT ID NUMBER

SITE ID

3rd Menstrual Cycle

Further details regarding daily medication or other comments/observations:

Day	Additional medication taken on this day for menstrual pain – details: *Record name, dose and frequency of medication taken each day. E.g. Ibuprofen 200mg, 1 tablet, 2 times a day.*	Any other medicines used, comments or issues to report (for this menstrual period): *For other medications: Record name, dose and frequency of medication taken each day and reason. E.g. Amoxicillin 250mg, 1 tablet, 3 times a day for a chest infection.*
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B YOUR DAILY DIARY

PARTICIPANT ID NUMBER | SITE ID | DATE OF TRIAL ENROLMENT

4th Menstrual Cycle

Start date of diary (Day 1):_____ / _____ / _____ **Start time** *(approx):* _____ : _____ **Day of the week:** _____

DD MM YYYY | Use 24-hr clock HH MM | Mon/Tue/Wed/Thu/Fri/Sat/Sun

DATE	DIARY DAY	'I feel well today' Considering all physical, mental and social aspects, circle One per row below to **which best indicates overall how well you feel today**:					Are you menstruating today? *(circle)* IF YES, PLEASE COMPLETE COLUMNS TO RIGHT ➔		MENSTRUAL PERIOD					
									STUDY TABLETS (TXA/Placebo) For each day/time of your period put number of tablets (e.g. "2") *[max. 5 days or 5x6=30 tablets]*			Total number of menstrual products used today i.e. bedtime to bedtime? [Enter number]	What was the worst menstrual pain that you experienced today on a scale of 0-10? [Enter number] 0 = no pain, 10 = worst imaginable pain	Any additional medication taken for menstrual pain? (tick ✓). If **yes**, record details on next page
									🌥	☀	🌙			
	1.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	2.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	3.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	4.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	5.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	6.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	7.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	8.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	9.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	10.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						

C YOUR DAILY DIARY (Continued)

PARTICIPANT ID NUMBER

SITE ID

4th Menstrual Cycle

Further details regarding daily medication or other comments/observations:

Day	Additional medication taken on this day for menstrual pain – details: *Record name, dose and frequency of medication taken each day. E.g. Ibuprofen 200mg, 1 tablet, 2 times a day.*	Any other medicines used, comments or issues to report (for this menstrual period): *For other medications: Record name, dose and frequency of medication taken each day and reason. E.g. Amoxicillin 250mg, 1 tablet, 3 times a day for a chest infection.*
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B **YOUR DAILY DIARY**

PARTICIPANT ID NUMBER | SITE ID | DATE OF TRIAL ENROLMENT

5th Menstrual Cycle

Start date of diary (Day 1):_____ / _____ / _____ **Start time** *(approx):* _____ : _____ **Day of the week:** _____

DD MM YYYY | Use 24-hr clock HH MM | Mon/Tue/Wed/Thu/Fri/Sat/Sun

DATE	DIARY DAY	'I feel well today' Considering all physical, mental and social aspects, circle One per row below to **which best indicates overall how well you feel today**:					Are you menstruating today? *(circle)* IF YES, PLEASE COMPLETE COLUMNS TO RIGHT ➔		MENSTRUAL PERIOD					
									STUDY TABLETS (TXA/Placebo) For each day/time of your period put number of tablets (e.g. "2") *[max. 5 days or 5x6=30 tablets]*			Total number of menstrual products used today i.e. bedtime to bedtime? [Enter number]	What was the worst menstrual pain that you experienced today on a scale of 0-10? [Enter number] 0 = no pain, 10 = worst imaginable pain	Any additional medication taken for menstrual pain? (tick ✓). If **yes**, record details on next page
														
	1.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	2.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	3.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	4.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	5.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	6.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	7.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	8.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	9.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	10.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						

PARTICIPANT ID NUMBER

SITE ID

5th Menstrual Cycle

Further details regarding daily medication or other comments/observations:

Day	Additional medication taken on this day for menstrual pain – details: *Record name, dose and frequency of medication taken each day. E.g. Ibuprofen 200mg, 1 tablet, 2 times a day.*	Any other medicines used, comments or issues to report (for this menstrual period): *For other medications: Record name, dose and frequency of medication taken each day and reason. E.g. Amoxicillin 250mg, 1 tablet, 3 times a day for a chest infection.*
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B **YOUR DAILY DIARY**

PARTICIPANT ID NUMBER		SITE ID		DATE OF TRIAL ENROLMENT	

6th Menstrual Cycle

Start date of diary (Day 1):_____ / _____ / _____ **Start time** ***(approx):*** _____ : _____ **Day of the week:** _____

DD MM YYYY Use 24-hr clock HH MM Mon/Tue/Wed/Thu/Fri/Sat/Sun

DATE	DIARY DAY	'I feel well today' Considering all physical, mental and social aspects, circle One per row below to **which best indicates overall how well you feel today**:					Are you menstruating today? *(circle)* IF YES, PLEASE COMPLETE COLUMNS TO RIGHT ➔		MENSTRUAL PERIOD					
									STUDY TABLETS (TXA/Placebo) For each day/time of your period put number of tablets (e.g. "2") *[max. 5 days or 5x6=30 tablets]*			Total number of menstrual products used today i.e. bedtime to bedtime? [Enter number]	What was the worst menstrual pain that you experienced today on a scale of 0-10? [Enter number] 0 = no pain, 10 = worst imaginable pain	Any additional medication taken for menstrual pain? (tick ✓). If **yes**, record details on next page
									🌥	☀	🌙			
	1.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	2.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	3.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	4.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	5.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	6.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	7.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	8.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	9.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						
	10.	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH	YES	NO						

C YOUR DAILY DIARY (Continued)

PARTICIPANT ID NUMBER

SITE ID

6th Menstrual Cycle

Further details regarding daily medication or other comments/observations:

Day	**Additional medication taken on this day for menstrual pain – details:** *Record name, dose and frequency of medication taken each day. E.g. Ibuprofen 200mg, 1 tablet, 2 times a day.*	**Any other medicines used, comments or issues to report (for this menstrual period):** *For other medications: Record name, dose and frequency of medication taken each day and reason. E.g. Amoxicillin 250mg, 1 tablet, 3 times a day for a chest infection.*
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D YOUR TRIAL SUPPLIES

At the Enrolment study visit you will be given the following:

- **Trial tablets:** 3 bottles/packs:

  Use the bottle numbered:

  Bottle 1 – for months 1 and 2

  Bottle 2 – for months 3 and 4

  Bottle 3 – for months 5 and 6

➔ **Please keep out of sight and reach of children!**

- **Iron and Folic acid pills/tablets/liquid** (standard anaemia treatments)

You have been given 3 month supply. Please start taking it on the day you were enrolled to the trial.

➔ **Please keep out of sight and reach of children!**

- **Packs of disposable period pads/towels:** supply for whole study period

➔ *(Note: These are for your personal use. If you need more pads, please let the study team know)*

- **Contact/Trial Card** (including contact information to schedule study visits, please also show this card whenever you have contact with healthcare providers outside of this study)

E ABOUT YOUR STUDY TABLETS

WHAT YOU NEED TO KNOW ABOUT THE STUDY TABLETS

The study tablets you have received are either Tranexamic acid (TXA) tablets or Placebo (dummy tablets that do not contain any active medicine). Neither you nor the study team know which you have been given.

TXA belongs to a group of medicines called anti-fibrinolytics. These are used to stop or reduce bleeding. When you bleed your body forms clots to stop the bleeding. Breakdown of the clots can cause too much bleeding. TXA stops these clots dissolving and so reduces the amount of bleeding. Bleeding can not only cause anaemia, but anaemia can also lead to heavier bleeding according to research.

TXA is used for many different conditions, including for heavy menstrual bleeding. We hope that our study will show that women who take TXA lose less blood during their periods and recover faster from anaemia.

WHEN TO TAKE YOUR STUDY TABLETS

The three bottles of trial medication are labelled **1, 2, 3.** Please use;
the **1st bottle** for your 1st and 2nd period,
the **2nd bottle** for your 3rd and 4th period and;
the **3rd bottle** for your 5th and 6th period.

Take **2 tablets, three times a day** from the first until the last day of your menstrual period, but no longer than 5 days. It is important that you start the tablets **as soon as your period is about to start**. (For example, if your period is about to start in the evening, take the first 2 tablets in the evening, rather than waiting until the next morning.)

If you forget to take your study tablets, do not take a double dose to make up for a missed dose. Simply take the next dose as planned.

Image of bottles to be inserted here

HOW TO TAKE YOUR STUDY TABLETS

Take your study tablets with a glass of water. The tablets should be swallowed whole. Do not crush or chew them.

HOW TO STORE THEM

Keep the study tablets out of the sight and reach of children. Do not use study tablets after the expiry date on the bottle. The expiry date refers to the last day of that month. Keep at room temperature.

RETURN OF EMPTY BOTTLES/PACKS AND ANY UNUSED STUDY TABLETS

After each period, please return the corresponding bottle/pack (with any unused tablets) to the study team at your next visit.

WHAT TO DO IF YOU HAVE ANY CONCERNS OR MEDICAL ISSUES

If you have any concerns or medical issues, please contact the study team. If you need urgent medical care, go to your nearest hospital and let the study team know as soon as possible.

If you accidentally take too many study tablets you may get side effects. These can include feeling or being sick, diarrhoea and feeling dizzy. Tell the study team or seek medical advice if you have taken too many tablets and if you feel worried about possible side effects.

Whenever you have contact with healthcare providers outside of this study, please show them the Contact Card.

ANY OTHER INSTRUCTIONS

Do not share your study tablets with anyone.
If you think you might be pregnant at any point during the study period, please contact the study team.
If you have any further questions about the use of the study tablets, please ask the study team.

F ABOUT YOUR IRON/FOLIC ACID ANAEMIA TREATMENT

The iron and folic acid supplements given to you are the standard treatment provided to people with anaemia. They provide essential nutrients that help your body produce healthy red blood cells to help treat your anaemia.

You have been given 3 month supply. Please start taking it on the day you were enrolled to the trial. Once you have completed the full 3 month supply, these 3 supplements will be stopped.

[EACH COUNTRY WILL NEED THEIR OWN INSTRUCTIONS ON WHEN AND HOW TO TAKE AND HOW TO STORE THE TABLETS/PILLS/LIQUID IN LINE WITH LOCAL STANDARD OF CARE AND/OR REFER PARTICIPANTS TO THE REGULAR PACKAGE INSERT/PATIENT LEAFLET]

POSSIBLE SIDE EFFECTS AND WHAT YOU CAN DO TO PREVENT/REDUCE THEM

It is normal to have dark/black stools when taking iron supplements. Some people can have nausea, upset stomach, constipation or diarrhoea. These side effects are usually mild and temporary. If you have an upset stomach, you can try taking the iron with food. If you get constipated, try drinking lots of water throughout the day and eat more vegetables, fruits and whole grain.

If this does not help, you can take less iron or stop taking it completely if needed.

Note: We will ask you during the study how you are managing to take the iron and folic acid treatment.

ANY OTHER

Do not share your supplements with anyone else.
[EACH COUNTRY WILL ADD THEIR OWN INSTRUCTIONS IF NEEDED AND/OR REFER PARTICIPANTS TO THE REGULAR PACKAGE INSERT/PATIENT LEAFLET]

G NOTES

Please add any other information you wish to record:

H PARTICIPANT FEEDBACK

To help us understand how the trial has been for you, we would be grateful for your feedback.
Please be as honest as possible. Your feedback will remain anonymous.

THANK YOU

On behalf of the WOMAN-3 trial team we would like to thank you very much for participating in this important research. After the visits, we will give you a gift for your time. The (total) value of the gift(s) will reflect the number of visits you made.
This is our way of saying thank you for your valuable contribution to this research.

1st Follow up appointment (Telephone)		
Planned date/time:	Attended? [ ] Yes, [ ] No	Staff initials:
Comment:		
2nd Follow up appointment (In-person visit)		
Planned date/time:	Attended? [ ] Yes, [ ] No	Staff initials:
Comment:		
3rd Follow up appointment (Telephone)		
Planned date/time:	Attended? [ ] Yes, [ ] No	Staff initials:
Comment:		
4th Follow up appointment (In-person visit)		
Planned date/time:	Attended? [ ] Yes, [ ] No	Staff initials:
Comment:		
5th Follow up appointment (In-person visit)		
Planned date/time:	Attended? [ ] Yes, [ ] No	Staff initials:
Comment:		
Final/6th follow up appointment (In-person visit)		
Planned date/time:		
Comment:	Attended? [ ] Yes, [ ] No	Staff initials:

Thank you gift(s)	
Date(s) and Type(s) Of gift(s) provided:	
Comment:	

woman3

Tranexamic acid for anaemia treatment trial

Participant's Diary and Information Booklet

Clinicaltrials.gov ID: NCT06519422;
WOMAN-3 Trial, Participant Diary - Version.2.0, 25 July 2025