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EAT-UP

Extended **A**ntibiotic **T**reatment in chronic **U**TI **P**atients; a phase II safety and efficacy trial

Participant Information Sheet

We would like to invite you to take part in our research, called the EAT-UP trial.

You have been given this information sheet because your doctor feels you may be suitable to take part. Before you decide if you would like to take part, it is important for you to understand why the research is being done and what it will involve for you.

Please take your time to read this information very carefully before deciding whether you would like to take part. Discuss it with your family or friends if you wish.

Ask your local research team if there is anything that is not clear or if you would like more information. A member of your team can go through this leaflet with you and answer any questions you have.

Part 1 tells you about the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

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Part 1

1. WHAT IS THE PURPOSE OF THIS RESEARCH?

Nearly 50% of women experience at least one Urinary Tract Infections (UTI) in their lifetime, with 40% of these facing recurrent infections, characterised by frequent infections with periods without symptoms. Some women develop chronic UTIs, a condition in which individuals experience persistent, daily symptoms.

The NHS currently lacks specific treatment guidelines for chronic UTI, as it has only been recognised as a separate type of UTI in recent years. As a result, treatment within the NHS is based on recommended guidelines for recurrent UTI. The standard approach typically includes one of the following treatments:

- Short courses of antibiotics at treatment (high) doses during symptom flares (where your symptoms are temporarily worse).
- Long-term courses of prophylactic (low) dose daily antibiotic (where medication is used at low doses to try to prevent symptoms reoccurring).
- Long-term use of a urinary antiseptic (which helps keep your urine bacteria free), called methenamine hippurate.

These often do not work for people with chronic UTI, and symptoms can persist. Moreover, standard urine tests may fail to detect infections, making diagnosis and treatment more challenging. Doctors are looking for a different treatment plan that may be more effective.

The aim of this trial is to find out whether taking higher dose antibiotics for an extended period of time in addition to the urinary antiseptic, methenamine hippurate is effective and safe for treating chronic UTI compared to the standard treatments where either long courses of low-dose antibiotic or methenamine hippurate is taken on its own.

2. WHY HAVE I BEEN INVITED TO TAKE PART?

You have been invited and may be eligible to participate in the EAT-UP trial as you have been diagnosed with a chronic UTI and have experienced symptoms for over 3 months.

We aim to recruit 192 participants who are female, aged 18 and older, from multiple hospitals across England for this trial.

3. DO I HAVE TO TAKE PART?

No. It is up to you to decide whether you want to join the trial. Your participation in the trial is completely voluntary. If you decide not to, you will receive whatever standard treatment you and your doctor decide is best and it will in no way affect the care you receive.

If you would like to participate, a member of the research team (your nurse or doctor) will discuss this information sheet with you. You will have the opportunity to ask any questions you may have and will be asked to sign the consent form for this trial. You will be given a copy of the signed consent form and this information sheet to keep. Even if you agree to take part, you are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

Not everyone will be able to take part in this trial. Only patients who meet all the trial entry requirements and are willing to participate may take part. Your trial doctor will assess your eligibility.

4. WHAT ARE THE MEDICINES BEING TESTED?

In this trial there will be **two** treatment groups:

A) High (treatment) dose antibiotic, **plus** urinary antiseptic methenamine hippurate

B) Low (prophylactic) dose antibiotic **or** urinary antiseptic methenamine hippurate

All medications being tested in the trial are licensed within the UK for treatment of UTI, however, one of the groups will be receiving an antibiotic at a higher dose for a longer period of time than usually prescribed.

For each group, a specific treatment will be prescribed from the options listed below:

Group A – Trial Treatment A choice of **one** of the below antibiotics at treatment dose **plus** a urinary antiseptic
Cefalexin 500mg, four times daily **OR** Nitrofurantoin 100mg, twice daily **OR** Trimethoprim 200mg, twice daily
PLUS
Methenamine Hippurate 1g, twice daily

Group B – Standard Treatment A choice of **one** of the below
Cefalexin 125mg, once daily **OR** Nitrofurantoin 50mg, once daily **OR** Trimethoprim 100mg, once daily **OR** Amoxicillin 250mg, once daily **OR** Methenamine Hippurate 1g, twice daily

The specific treatment you receive within your allocated treatment group will be determined by your local doctor who will base this decision on your medical history, known allergies and what would be most suitable for you.

If you experience any side effects to the medications you are taking, your treatment can be adjusted. For example, if you experience a side effect to an antibiotic this can be switched

to a different option from the same group. The dose of the new medication must match the dose used in your assigned treatment group.

All medications are to be taken orally, and you will take the treatment for 12 weeks.

If you are prescribed antibiotics by another doctor, such as your GP or dentist, for any reason (for example, to treat a different infection), you must stop taking your trial medication(s) while taking the newly prescribed antibiotics and contact your research doctor/team immediately, as it may be harmful to take both medications at the same time.

5. WHICH TREATMENT GROUP WILL I BE IN?

Sometimes we don't know which treatment option is best and we need to compare different treatments. To find out if taking a high dose antibiotic and methenamine hippurate for an extended period of time is an effective treatment for chronic UTI, we will put participants into 2 groups and give each group a different treatment (as shown above). The results of each group will be compared to see if one is better. Half of the participants will receive an antibiotic at high dose with methenamine hippurate and half will receive the current standard treatment of either an antibiotic at low dose or methenamine hippurate.

Participants will be randomly allocated to a treatment group using a computer system (similar to tossing a coin). This process is called 'randomisation'. This means you will not be able to choose your group, however, you will be informed of which group you are allocated to.

6. WHAT DOES THE EAT-UP TRIAL INVOLVE FOR ME?

If you wish to take part, you will be invited to attend a **'Screening Visit'** where your local research team will assess you to make sure that you are suitable for this trial. During this visit, you'll have the chance to ask any questions you may have about the trial and if you are happy to do so you'll be asked to give your informed consent. You will be asked some questions about your condition, your medical history, any medication that you are taking, and you will also undergo several assessments. These assessments will include:

- Checking your heart rate, blood pressure, temperature and breathing rate.
- Performing a physical examination.
- Performing a blood test to ensure it is safe for you to participate in the trial.
- Performing urine testing, including dipstick analysis and urine microscopy.
- If you are able to have children, a pregnancy test will be performed. This will be repeated **at all trial visits**.

These assessments and tests will take approximately an hour and a half for most patients. A member of the research team will be with you during these assessments to make your time in the hospital as smooth as possible.

The research team will confirm whether you meet all the entry requirements for the EAT-UP trial within two weeks of your screening visit. If you meet all the entry requirements, your team will ask you to return to the hospital for **Visit 1**.

At **Visit 1** you will be randomly allocated into one of the treatment groups.

If you are allocated to **Group A** you will take **two** different medications. You will receive one of the following antibiotics at a high dose:

- Cefalexin 500mg to be taken four times a day
- Nitrofurantoin 100mg to be taken twice a day
- Trimethoprim 200mg to be taken twice a day

In addition, you will also take Methenamine Hippurate 1g twice a day.

If you are allocated to **Group B** you will take **one** medication. You will receive one of the following medications:

- Cefalexin 125mg to be taken once a day
- Nitrofurantoin 50mg to be taken once a day
- Trimethoprim 100mg to be taken once a day
- Amoxicillin 250mg to be taken once a day
- Methenamine Hippurate 1g twice a day

The following assessments and tests will then be performed:

- A check of your heart rate, blood pressure, height, weight, temperature and breathing rate.
- Physical examination.
- Blood and urine tests at your local hospital.
- Additional urine collection and a swab taken from the skin between your vagina and anus (which you can either complete yourself or with assistance from your local research team) for testing at the trial's research laboratory.
- You will be asked to complete several questionnaires about your symptoms and general quality of life.
- If you are able to have children, a urine pregnancy test.

Following Visit 1, you will have follow-up visits every 4 weeks: Visit 2 (week 4), Visit 3 (week 8), and Visit 4 (week 12). After the final visit (Visit 4), you will stop taking the trial medication.

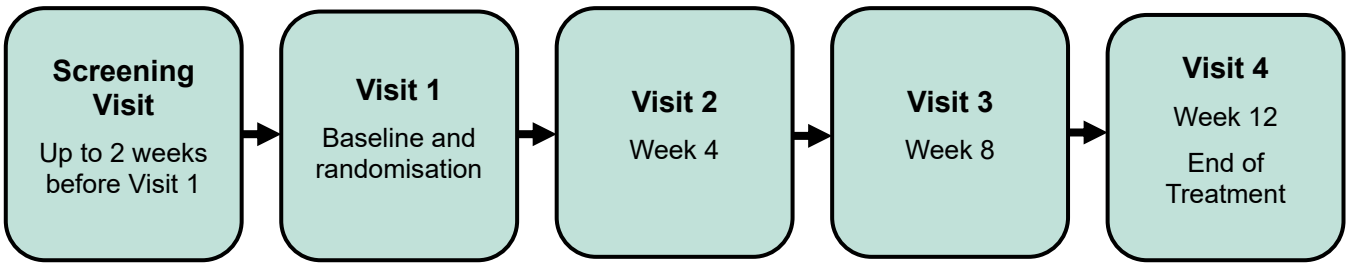
The following assessments and tests will be performed at these visits:

- A check of your heart rate, blood pressure, temperature and breathing rate.
- Physical examination.
- Blood and urine tests.
- You will be asked to complete several questionnaires about your symptoms, overall quality of life, and your experience with taking the trial medication.

- If you are able to have children, a urine pregnancy test.

Your research team will also ask if you have experienced any side effects or changes to any other medications you're taking.

At your final visit **(Visit 4)**, an additional urine sample and a swab taken from the skin between your vagina and anus (which you can either complete yourself or with assistance from your local research team) will be collected for testing at the trial's research laboratory.



You will receive trial medication at Visits 1, 2, and 3. At each of these visits, you will be given a paper diary to record the medication you take, any missed doses, and any side effects you experience. You will also need to bring all your trial medication and packaging (both used and unused) to each trial visit. The research team will check how much medication you have taken and review the information in your diary.

The assessments at each trial visit will be the same for both treatment groups throughout the trial duration and will take approximately 1 to 1 and a half hours to complete for most patients.

If your UTI symptoms get worse or you experience any concerning side effects between scheduled trial visits, you may be asked to attend additional, unscheduled visits. During these visits, your local doctors will assess your symptoms and carry out any necessary tests. If a change to your prescribed treatment is needed, it will be made during that visit.

In cases where your symptoms suddenly become more severe, your doctor may prescribe a 'rescue therapy.' This could involve increasing the dose of your current antibiotic or prescribing a new antibiotic for a short period to manage the symptoms.

<u>Urine testing</u>

The NHS uses rapid urine dipstick analysis and urine cultures as standard to identify UTI. Research has shown that for individuals with chronic UTI these tests can sometimes miss infections. For research purposes the EAT-UP trial will look at your urine samples using a microscope called 'fresh urine microscopy' to accurately detect infection. Your local team will conduct any further standard tests that are required for your care.

Urine microscopy allows researchers to measure the number of white blood cells (WBCs) present in your urine. Research has shown that the presence of WBCs within urine is a good indicator of infection within the urinary tract. As such, at each visit you will provide a urine sample that your local research team will place under a microscope and take images of. These images will then be sent to the trial's central laboratory within the Centre for Kidney

and Bladder Health at University College London for analysis of the cells present within your urine. These results will be shared with your local clinician and research team.

Swab testing

At visits 1 and 4, a swab will be taken from the area between your vagina and anus (this area is called the perineal area). You will be able to complete this yourself or with assistance from your local research team. The swab will be sent to the central laboratory within the Centre for Clinical Microbiology at University College London for testing. The lab will look at the sample to check for any changes in how bacteria in your gut respond to antibiotics (also known as antimicrobial resistance).

7. WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

All medical procedures involve some risk, but this is usually low. It is possible that there could be risks associated with this trial that we do not know of yet. Information on the most common or serious side-effects of procedures carried out in this trial are listed below. If you have questions about side-effects or risks, please ask your trial doctor.

Blood samples: The collection of blood samples can be uncomfortable but rarely results in any serious problems. Reported side effects include feeling light-headed or faint, bruising and/or discomfort around the needle site. Every effort will be made to minimise this. Blood samples will be taken at every visit. The volume of blood collected will be up to 20mls (about 4 teaspoons).

Pregnancy and breastfeeding: Some of the trial medications if given to a pregnant participant, could harm the unborn child, and if given to participants who are breastfeeding can harm the child. Therefore, pregnant participants and participants who are breastfeeding must not take part in this trial.

Participants who are of childbearing potential (participants who could become pregnant) who do not agree to have urine pregnancy testing done as per the visit schedule for the duration of this trial will not be allowed to take part in this research.

If you are of childbearing potential, you must use a appropriate contraceptive method to avoid pregnancy for the whole duration of this trial, and for 1 week after your final trial visit. Appropriate contraceptive method include hormonal contraception, intrauterine device, bilateral tubal occlusion or abstinence, if preferred and usual lifestyle of the participant. If necessary, please discuss contraception with your trial doctor to ensure that it is acceptable.

Participants of childbearing potential that are considering becoming pregnant should not take part in this trial. Participants who are unable or unwilling to use an appropriate method of contraception to avoid pregnancy for the duration on this trial and for 1 week after the last dose of trial medication will not be allowed to take part in this research.

If you become pregnant, you must stop taking your trial medication and contact your research doctor/team immediately. Key contact information can be found at the end of this information leaflet. Your research doctor/team is required to inform the trial sponsor at UCL that you have become pregnant, however, sharing further details about your pregnancy is entirely optional.

If you agree, you will be provided with a Pregnancy Information Sheet and Consent Form to review and sign. You are free to decide whether or not to provide this information, and your choice will not affect your ongoing participation in the trial or care.

Other risks: All efforts are made to make this trial safe. Despite this, some risks might not be possible to predict.

8. WHAT ARE THE SIDE EFFECTS OF THE TRIAL MEDICATION?

In any clinical trial, there is a chance of experiencing side-effects from the trial medication. Research has shown that all medications used in this trial are usually well-tolerated and the common side effects have been listed below.

If you experience any unpleasant side effects, whether listed below or not, you should report them to the research team at your next trial visit or contact them if you have any concerns.

Antibiotic Side Effects

During the trial, you may be given one of the following antibiotics: Amoxicillin, Cefalexin, Nitrofurantoin, or Trimethoprim. Like all antibiotics, these can cause some common side effects, including:

- **Digestive issues:** Diarrhoea, feeling sick, indigestion or vomiting.
- **Skin conditions:** Rashes, hives, or itchiness.
- **Infections:** Yeast infections.
- **Abnormal blood results:** Some of these antibiotics can cause changes to the levels of proteins within your blood, particularly ones that are linked to your liver and kidneys. Additionally, some may affect your platelets, white blood cells and red blood cells. These will be checked at each of your trial visits.
- **Headaches**

On rare cases, some people may experience an **allergic reaction** to an antibiotic, ranging from mild skin rashes and itching, to coughing, wheezing, or throat tightness, which can make breathing difficult. These symptoms are usually treated with antihistamines. If you experience any of these symptoms, contact your local research team or other health care professionals immediately for guidance.

Some of these antibiotics can cause specific side effects as listed below:

<u>Trimethoprim:</u>

Trimethoprim commonly (in more than 1 in 10 people) increases potassium levels in the blood. High potassium levels in your blood can be harmful because they affect how your heart and muscles work. This can cause irregular heartbeats, muscle weakness, or, in severe cases, heart problems that can be life-threatening. Your blood potassium levels will be monitored at each trial visit.

Nitrofurantoin:

In very rare cases, Nitrofurantoin can cause lung problems (acute pulmonary damage), leading to breathing difficulties, coughing, chest pain, or low oxygen levels. Your research team will closely monitor you for these symptoms. If you notice any of these signs, contact your doctor immediately.

Methenamine Hippurate

During the trial you may receive the antiseptic Methenamine Hippurate (either on its own or in combination with an antibiotic). Common side effects (affecting up to 1 in 10 people) include:

- **Digestive issues:** Feeling sick and vomiting.
- **Skin conditions:** Skin rashes – mild red or bumpy rash.
- **Bladder issues:** Bladder irritation.

If you take part, you will be given a Participant Trial Card to carry at all times, saying you are taking part in this trial. If you experience any side effects, you can show this to the doctors before they give you any treatment.

If your UTI symptoms worsen during the trial and you need extra treatment, your local research team may prescribe a short course of additional antibiotics called rescue therapy. They will also explain any possible side effects of these medications

9. WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

We hope that all trial treatments will help you, but this cannot be guaranteed. The information we get from this trial will help us understand how to treat future people with chronic UTI better.

10. WILL I BE PAID?

You will not be paid for taking part in this trial, however, the costs you (and if applicable, a carer) incur for travel and refreshments will be reimbursed up to a total of £45 for each visit (visit 1-4 only). Please keep all relevant receipts as you will need to provide these to the research team at your hospital.

11. WHAT HAPPENS WHEN THE RESEARCH STOPS?

If you are allocated to **Group A** of the trial, you will receive treatment dose antibiotics for 12 weeks (3 months) as part of the trial. After this, if the treatment is still helping and your doctor believes it could still benefit you, you may be offered up to an additional 9 months of treatment dose antibiotics through your local NHS service, such as a LUTS (Lower Urinary Tract Symptoms), urology, or urogynaecology clinic. You may also be prescribed Methenamine Hippurate, if needed.

If continuing the treatment, you received as part of the trial locally is not possible, you may be referred to the Whittington Hospital in London (unless the Whittington Hospital is already your local hospital). To help avoid delays, this referral will be sent at the start of the trial. However, it is completely your choice whether you wish to continue treatment and use this referral after your trial participation ends.

If you are allocated in **Group B** of the trial, after your 12-week follow-up, you will continue to receive any treatment you need as part of your usual NHS care at your local hospital.

12. WHAT IF THERE IS A PROBLEM?

If you have a concern about any aspect of this trial, you can talk to your local research team who will answer your questions. Key contact information can be found at the end of this leaflet. If you're still unhappy and wish to complain formally, you can. Details of how to complain can be obtained from your hospital.

Every care will be taken in the course of this trial, however in the unlikely event that you are injured by taking part, compensation may be available.

If you suspect that the injury is the result of the Sponsor's (UCL) or the hospital's negligence, then you may be able to claim compensation. After discussing with your local research team, please make the claim in writing to Dr Rajvinder Khasriya who is the Chief Investigator of the EAT-UP trial. They will then pass the claim to the Sponsor and insurers. If you have a claim, then it might be helpful to consult a lawyer.

Participants may also be able to claim compensation for injury caused by participation in this trial without the need to prove negligence on the part of UCL or another party. You should discuss this possibility with your local research team doctor in the same way as above.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any adverse events (side effects) you may have experienced due to your participation in this trial, the normal NHS complaints mechanisms are available to you. Please ask your trial doctor if you would like more information on this. Details can be obtained from the NHS website.

Alternatively, you can contact the Patient and Advice and Liaison Service (PALS) at the hospital:

Telephone: 020 7288 5551

Email: whh-tr.pals@nhs.net

Address: PALS Office, Whittington Hospital, Magdala Avenue, London, N19 5NF

If following the information in Part 1 you are considering participation in the EAT-UP trial, please read the additional information in Part 2 before making any decisions.

Part 2

1. WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

During a trial, new information sometimes becomes available about the medicines that are being studied. If this happens, your doctor will discuss with you whether you want to continue in the trial. If you decide to stop taking part, your doctor will arrange for your care to continue outside of the trial.

Your doctor might also suggest that it is in your best interests to stop taking part and will explain the reasons and arrange for your care to continue outside of the trial. If you decide to continue in the trial, you may be asked to sign an updated consent form.

2. WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE TRIAL?

You are free to withdraw from the trial at any time without giving any reason, although it may be helpful to talk to a member of your local research team first as they can advise you about any concerns you may have. All information and samples collected up until the time of withdrawal will be included in the trial analysis.

If you wish to stop taking the trial medication only but are happy to continue to be followed up, we will ask you attend the remaining trial visits as this is still helpful for the trial and helps us to ensure that the results are reliable.

If you choose to withdraw from the trial completely, and do not want us to contact you again, it is within your right to do so. No more information will be collected about you.

A decision not to take part or a decision to stop taking part at any time will not affect the standard of care you receive.

3. WILL MY GP BE INFORMED OF MY INVOLVEMENT IN THIS TRIAL?

With your permission, we will let your general practitioner (GP) know that you are taking part in this research. Your local research team will send a letter with a copy of this information sheet to inform them of your participation in this trial.

4. WHAT WILL HAPPEN TO ANY SAMPLES I GIVE?

During the trial, routine blood and urine samples (as part of standard care), as well as research urine samples and swabs taken from the skin between your vagina and anus (which you can either complete yourself or with assistance from your local research team) will be collected from you at various visits (see summary of assessments at the end of this document).

The routine blood samples and urine will be tested at your local hospital and will be labelled with your identifiable information (name, date of birth) in accordance with local hospital Trust policy. Once the blood samples have been analysed, any remaining excess will be disposed of as per your hospital's local policy.

Research specific urine and swab samples will be analysed outside of your hospital and will be labelled with a unique trial number and your partial date of birth, therefore your identifiable

information will not be available to anyone outside of the research team. Urine and swab samples will be sent to the Centre for Clinical Microbiology at University College London for analysis. Images taken of your urine during microscopy will be sent to the Centre for Kidney and Bladder Health for analysis. The collection of these samples and images from chronic UTI participants across multiple UK sites and at multiple timepoints will provide valuable insight for future research on chronic UTI and its response to treatments.

We will also ask for your permission to donate any remaining urine or swab samples, and use images taken of your urine under a microscope taken as part of the trial to be used for future chronic UTI research, either at academic sites nationally or internationally, or in academic collaborations with commercial partners. The donation of your samples, and images of your urine is completely optional and will not affect participation in the trial if you do not wish to donate. Data will only be shared among approved researchers. These samples and images will be stored in laboratories and each sample will be labelled with a unique trial number and your partial date of birth (month and year), therefore your identifiable information will not be disclosed. Unfortunately, we are not able to disclose the results of these analyses to participants.

5. WILL ANY GENETIC TESTS BE DONE?

No genetic tests will be performed as part of this trial.
Local and research samples will be collected as described above.

6. WHO IS ORGANISING AND FUNDING THIS RESEARCH?

This trial is organised by the Comprehensive Clinical Trials Unit (CCTU) at University College London (UCL). The trial coordination, data collection from the sites, analysis and administration will be provided by the CCTU at UCL. You can find out more about us at https://www.ucl.ac.uk/cctu.

Funding for this research has been provided by the Medical Research Council (MRC). You can find out more about the MRC at https://www.ukri.org/councils/mrc/.

Your trial doctor is not receiving any money or other payment for asking you to take part in the trial.

7. WHO HAS REVIEWED THIS RESEARCH?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by Wales Research Ethics Committee 3.

This trial has also been reviewed and authorised by the Medicines for Healthcare Products Regulatory Agency (MHRA).

The Research and Development (R&D) department at your hospital has also given permission for this research to happen.

8. WHAT WILL HAPPEN TO THE RESULTS OF THIS RESEARCH?

The summary of the overall trial results will be shared with you before being published on the UCL CCTU website at https://www.ucl.ac.uk/cctu. The researchers will share the trial data on an openly accessible website and in medical journals. Your identity and personal details will be kept confidential. No named information will be published about you on any websites or in any reports.

9. HOW WILL WE USE INFORMATION ABOUT YOU?

We will need to use information from your medical records for this research project.

This information will include your initials, NHS number, name, partial date of birth (month and year) and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. If you are not contactable, researchers at your local hospital will use your NHS number or other identifiers to access your medical records to obtain your contact details.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

University College London (UCL) is the sponsor of this research, based in the United Kingdom, and has delegated some of their responsibilities as Sponsor to the Comprehensive Clinical Trials Unit (CCTU) at UCL. UCL CCTU is responsible for looking after your information. We will keep all information about you safe and secure by:

- Collecting only non-identifiable information: Any data we receive about you will not include your name, NHS number, contact details, or any other identifying information. Instead, your data will be linked to a unique trial code.

- Ensuring data protection compliance: The CCTU is registered under the UK Data Protection Act (DPA).

- Adhering to strict data protection standards: We follow the UCL Data Protection Policy to ensure full compliance with all applicable data protection laws.

International transfers

For this trial your data will not be shared outside the UK.

How will we use information about you after the study ends?

Once we have finished the trial, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the trial.

We will keep your trial data for a maximum of 25 years. The trial data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the trial at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the trial, we would like to continue collecting information about your health from your hospital and/or your GP. If you do not want this to happen, tell us and we will stop.
- you have the right to ask us to remove, change or delete data we hold about you for the purposes of the trial. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree to take part in this trial, you will have the option to take part in future research using your data saved from this trial.

Where can you find out more about how your information is used?

You can find out more about how we use your information by using the following resources:

- By asking a member of your local research team.
- In our leaflet 'How health researchers use information from participants in clinical trials' available from https://www.ucl.ac.uk/comprehensive-clinical-trials-unit/use-data
- HRA link for further information: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/
- At the link https://www.ucl.ac.uk/legal-services/privacy/ucl-general-privacy-notice-participants-and-researchers-health-and-care-research-studies
- By sending an email to the UCL Data Protection Officer on data-protection@ucl.ac.uk
- By contacting cctu-enquiries@ucl.ac.uk
- UCL Data Safe Haven: https://www.ucl.ac.uk/isd/services/file-storage-sharing/data-safe-haven-dsh.

10. WILL MY PARTICIPATION IN THIS RESEARCH BE KEPT CONFIDENTIAL?

Yes, we will follow ethical and legal practices and all information about you will be handled in confidence. All information which is collected about you during the course of the research will be kept strictly confidential and any information about you which leaves the hospital will not have your name and address to ensure that you cannot be recognised. Your confidentiality will be safeguarded during and after this trial.

Certain individuals from the Sponsor's office and responsible persons authorised by the Sponsor, including the UCL CCTU, regulatory authorities and NHS Trusts, may look at parts of your medical records and data collected where it is relevant to you taking part in this research. This is to ensure the trial is being conducted right and to check the accuracy of data and adherence to the trial protocol. These individuals have a duty of confidentiality towards you.

11. FURTHER INFORMATION AND CONTACT DETAILS

If you have any further questions about the EAT-UP trial, please contact your local research team:

- Name: Sarah-Kate McLeavey
- Role: Local Collaborator
- Email: whh-tr.researchanddevelopment@nhs.net
- Telephone number: 020 7288 3585

If you decide you would like to take part, please read and sign the consent form. You will be given a copy of this participant information sheet and the informed consent form to keep. A copy of these documents will also be filed in your medical notes, and one will be filed with the trial records. You can have more time to think about your participation in the EAT-UP trial if you are unsure about anything.

Thank you for taking the time to read this information sheet and considering this trial. You should ask questions about anything that you do not understand before signing the informed consent form. The trial research staff will answer any questions.

EAT-UP Trial – Summary of Visits and Assessments

Screening Visit

- Discuss trial with doctor and sign consent form
- Review of medication, vital signs, physical examination, medical history, urine tests, and blood tests
- Urine pregnancy test for women of childbearing potential

Visit 1

- Review of medication, vital signs, height and weight measurements, physical examination, urine and blood tests, and a swab taken from the skin between your vagina and anus (which you can either complete yourself or with assistance from your local research team)
- Urine pregnancy test for women of childbearing potential
- Complete questionnaires
- Randomisation to Group A or B
- 4-week supply of trial medication provided
- Medication diary provided to all participants for completion at home

Visit 2, Week 4

Visit 3, Week 8

At Visits 2 and 3:

- Review of medication and medication diary, side effects, vital signs, physical examination, urine and blood tests.
- Urine pregnancy test for women of childbearing potential
- Complete questionnaires
- Further 4-week supply of trial medication provided
- New medication diary provided for completion at home

Visit 4, Week 12 (Final Visit)

- Review of medication and medication diary, side effects, vital signs, weight measurements, physical examination, urine and blood tests, and a swab taken from the skin between your vagina and anus (which you can either complete yourself or with assistance from your local research team)
- Complete questionnaires
- Urine pregnancy test for women of childbearing potential