ALternatives To prophylactic Antibiotics for the treatment of Recurrent urinary tract infection in women

Short Patient Information Sheet

This leaflet gives some brief information to people who may want to think about taking part in a NHS research study called the ALTAR Trial.

What is the purpose of the study?

- When antibiotics are used too often they can become less effective at treating infections and the bugs causing the infection can eventually become resistant to antibiotics. This means that the treatment may no longer work.

- Doctors would like to use fewer antibiotics where possible to prevent bugs from becoming resistant, but they need to be able to use another treatment that they know will work at least as well if not better than the antibiotics.

- The ALTAR trial is about finding out whether taking a non-antibiotic drug known as Methenamine Hippurate or Hiprex® twice a day is as good at preventing repeated urinary infections in women as taking a once daily dose of antibiotic (antibiotic prophylaxis).

Why have I been given this information?

- We have invited you to take part because you have had repeated urinary infections that you and your doctor agree require treatment.

What will happen to me if I take part?

- When doctors don't know which way of treating patients is best we compare different treatments directly to find out. We put patients into groups and give each group one of the different treatments. To try to make sure the groups are the same to start with each patient is put into a group by chance using a computer program. This is called **randomisation.**

- If you agree to take part, we will ask you to sign a consent form and then you will be put into one of the two groups (randomised). One group will be given a once daily antibiotic for a year (prophylaxis), whilst the other group will take Methenamine hippurate twice daily (Morning and Evening) for a year. We will monitor you for a further 6 months after you have finished your treatment to see which treatment is best at preventing the infections from coming back.

- During the course of the study (twelve months of treatment and for six months after you finish treatment) we will ask you to keep a simple diary of any symptoms of urinary infection. We will also ask you to complete a short health questionnaire every 3 months and at any time you have symptoms of a urinary infection. When you finish

The ALTAR Trial is funded by the National Institute for Health Research's HTA Programme

treatment after 12 months and again after 15 and 18 months we will ask you to fill out a questionnaire about how satisfied you are with the treatment you received.

- We also intend to collect some samples from you during the study. This will consist of a total of:
    - 7 urine samples – one at the start of the study and one each time you attend for a follow-up visit (every 3 months).
    - 7 blood samples one before treatment begins and then after 3, 6, 9 and 12 months of treatment. There will also be a requirement for 2 additional blood samples in the 6 months after you finish your treatment, one at 15 months and one at 18 months after randomisation.
    - 4 **optional** rectal or perianal swabs – one at the start of the study and one at the 6, 12 and 18 month visits.

- With your permission, we'd like to collect information from your healthcare records that relates to the research. Only individuals connected to the study would have access to these records and all information would remain strictly confidential.

- It is possible you may experience some side effects as a result of taking the antibiotics or the methenamine hippurate in this study. Most people don't have any, but there is more detail on possible side effects in the main patient information sheet for the study.

Do I have to take part?

- You don't have to take part unless you want to do so; your decision will not affect the care you receive from your doctors and nurses. If you agree to take part and change your mind later, you can withdraw from the study at any time. We cannot guarantee that the study will benefit you personally.

If you would be interested in taking part in this study to find out more please contact:

Name:

Email:

Telephone: