



ALTAR: Information for participants randomised to **antibiotic prophylaxis**

Introduction

This leaflet gives you some further information about your contribution to the ALTAR trial and we hope it will answer some of your immediate questions. We really need to know how you get on during the trial, particularly concerning the daily antibiotic treatment, any urinary infections you may have and details of other antibiotics that you may use. It is also very important that you stay on antibiotic prophylaxis for the whole year if you can and we are here to help you with any problems. Your local research team [INSERT NAME OF LOCAL TRIAL CONTACT] will keep in touch with you at least every three months over the next 18 months and please don't hesitate to contact us (details are at the end of this leaflet) if you have anything that you need to tell us, or any questions that you need answering.

ALTAR Antibiotic Prophylaxis Group: "Frequently Asked Questions"

I have been randomised to take daily antibiotic prophylaxis for a year: what happens next?

The research team member who went through the consent process with you will arrange an appointment in the near future for you to see your usual doctor (or a specialist nurse). At this appointment your doctor will check all your details and kidney function blood results to make sure it is alright for you to take a daily dose of antibiotics. This may be done at the same time as consent and randomisation if results are available. Next, you and your doctor decide which one of the three possible antibiotics (nitrofurantoin, trimethoprim or cefalexin) you should take.

How will it be decided which daily antibiotic I should take?

The choice of antibiotic that you take out of the three suggested options is up to you and your doctor. The choice will depend on how well you may have tolerated any of them in the past, your kidney function, any drug allergies you may have and the sensitivity of the bacteria that have caused your urinary infections in the past. Once the choice has been made, the doctor will give you a three month supply of the chosen antibiotic. Your local research team will contact you after a month to check all is well with taking the chosen antibiotic each day.

When should I take the daily dose of antibiotic?

You should take the antibiotic tablet last thing at night with a fluid drink.

What happens if I get a bad reaction to the first choice antibiotic?

All medicines that you have to take regularly may cause side effects. If you have a mild reaction like feeling a bit sick or having diarrhoea, we would like you to phone your local trial research team contact to tell them what has happened. They will then advise whether you should carry on taking the tablet or swap to a different one. If the problem is more severe and you feel very unwell, you should ring your GP during the daytime in the week, or ring the NHS helpline 111 at night time or during the weekends for advice. For any serious emergencies you should dial 999 and ask for an ambulance. Once you have the advice about what to do you should also phone your local trial research team contact as soon as possible to tell them what has happened. In any event it is likely that we will ask your doctor to take you off the original antibiotic and give you a supply of one of the others to try. You can then try the second type of antibiotic and your local research team will keep in touch with you to check that you are managing alright taking it each day.

How do I get further prescriptions for the antibiotic?

You will pick up your prescription from your hospital doctor every 3 months at your scheduled follow-up visits. If for any reason you think that you may run out of antibiotics please contact the hospital so that arrangements can be made to continue your supply.

Can I use other treatments to prevent infection or relieve infection symptoms?

We are very happy for you to continue to use other ways apart from antibiotics to help reduce the number of urinary infections that you get or even to try new things. We know that drinking plenty of fluid (about 2 litres) every day can help. For women the use of oestrogen hormone cream or pessaries put around the entrance to the vagina may help prevent urinary infections. Other options that some people feel help but for which there is no conclusive evidence of benefit are use of cranberry products, other chemicals that make the urine less acid such as potassium citrate or sodium bicarbonate, drinks that may have anti-bacterial properties such as nettle tea, and use of probiotic food or drinks such as 'live' natural yoghurt that helps keep up the level of healthy bugs in the gut. We will ask you about your use of these things in the trial questionnaires.

What happens if I get a urinary infection despite the daily antibiotic?

It is important that you take your usual actions when you get your typical symptoms of a urinary infection. You are probably the best judge of when you may need a full dose of antibiotic and you should seek medical help in your usual way by seeing your GP or going to another NHS clinic. You should send us a urine specimen in the supplied container and envelope before starting treatment and put one in to your GP's surgery. If you use 'self-start' therapy then you should use that in your usual way. When you are on this treatment dose of antibiotic you should stop your once daily prophylaxis dose but restart taking it the day you finish the infection treatment antibiotic. Sometimes you may need to switch to a different once daily antibiotic if the infecting bug has become resistant to the one you were taking originally. Your doctor and the local research team will help you organise this if needed. It is also vital for the trial results that you tell us when you get a urinary infection that needs treatment with a full dose of antibiotic and if you change the type of once daily antibiotic that you are using. We would like you to fill in a short questionnaire that has been supplied to you as part of the trial when you get an infection and let your local research team contact know as soon as you can when you are feeling better.

What if I become pregnant?

If you fall pregnant during the study it is very important that you let your GP and the local trial research team know as soon as possible. They will need to discuss with you about whether you can stay in the trial and whether you need to continue to take once daily antibiotic prophylaxis.

Can I continue the treatment after the end of the study?

It is usual for your doctor to advise you to stop taking the daily antibiotic after a period of one year and this will apply in the ALTAR study. We would encourage you to have six-months at least off preventative treatments once you have completed the 12-months of daily antibiotics. You will be closely monitored during this period and if your urinary infections occur then it may be necessary to consider further treatment. Women will sometimes experience a "breakthrough" infection after completing an extended course of preventative antibiotics and we would only recommend further treatment if the infections became recurrent.

Please don't hesitate to contact your local research team if you have any further questions or need to clarify anything.

Local Principal Investigator
Address

Local Research Nurse
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Phone:
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Phone:
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