



Participant Information Sheet

MERIT: D-MannosE to prevent Recurrent
urinary InfecTions

Can you help?

We would like to invite you to take part in our research
study.

Before you decide, it is important that you understand
why the research is being done and what it would involve
for you. Please take time to read this information, and
discuss it with others if you wish. If there is anything that
is not clear, or if you would like more information, please
ask us.

Why are we doing this study?

We aim to find out if women who take the food supplement D-mannose over a six-month period experience fewer, or less severe urinary tract infections (UTIs).

D-mannose, a form of sugar, is sold as a food supplement. Some women find it very helpful in reducing the number of UTIs they experience, but others don't. Previous research suggests that using D-mannose can reduce the number of UTIs experienced by women who have frequent UTIs. However, the studies were small and not well designed. We aim to recruit 508 women to take the supplement or a placebo for six months. Our results should then give us the confidence to advise women who suffer with recurrent UTIs whether D-mannose might be helpful to manage their condition.

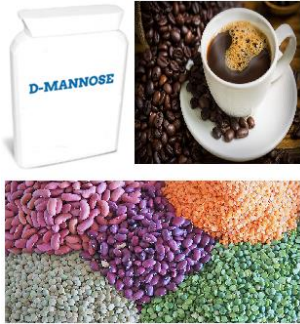
Why am I being asked to take part?

You have been invited to take part because you are aged over 18 and your GP medical records suggest that you have had at least two UTIs in the last six months or at least three in the last year.

What will happen if I decide to take part?

After completing eligibility, consent and a short questionnaire you will be assigned randomly to receive either D-mannose powder or placebo powder that you'll take once a day for six months. In this study the two powders are similar in terms of colour, taste and consistency and you will not know whether you have been given the placebo or D-mannose, nor will the study team or your nurse or doctor. We will also ask you to consent to us looking at your medical notes. You can contact the team to discuss the study, and have any questions answered.

What is D-mannose?



D-mannose is a form of sugar which is found naturally in the diet in foods like coffee, egg white, fruits and legumes. It is sold as a food supplement and is claimed to help prevent UTIs. We ask you to take 2 grams (1 level scoop) each day by stirring it into a drink or putting on top of your breakfast in such a way that you consume all of the powder. This contains 7.5 kcal so should not affect your normal diet. The placebo also contains 7.5 kcal per 2 grams which is about the same as 1/6 of an apple. D mannose can come in a variety of different powder forms.

What is the placebo?

The placebo in this study is a low calorie sugar – based powder that is not believed to have any effect on recurrent UTI. By giving half of our participants a placebo, we can make sure that any benefits we see are not just by chance.

Who is paying for and running the study?

The study is financed by the National Institute for Health Research. Funds have been allocated to the University of Oxford's Department of Primary Care Health Sciences. The sponsor of the study is the University of Oxford and Dr Gail Hayward is the Chief Investigator.








Has anyone reviewed the study?

The study has been approved by South West – Central Bristol Research Ethics Committee (reference number: 18/SW/0245).

Follow up

We will keep in regular contact with you from the time you start taking the powder to when you stop.

We will:

-  **Contact you once a week** to see if you are managing to take the study product and to see if you experienced a UTI
-  **Call you after a month** to see how you are getting on and may ask you a few questions if you experienced a UTI; and then every month if needed
-  If you experience a UTI, we ask you to **complete a short online or paper symptom diary** every day, until the UTI symptoms stop
-  After about two months at a time when you are symptom free we ask that you **send us a urine sample** in the pot and packaging provided to you
-  If you do go to your GP with a UTI we ask that you **give an additional sample** and send this to our laboratory. We will also ask for a sample two days after your UTI symptoms have cleared as well. Your GP will continue to provide you with standard treatment should you experience a UTI during the study.
-  At the end of six months participation **we will complete a review of your medical records and ask you to fill in one last form about your experience in the study**
-  A small number of participants who have agreed to this will be contacted for an **optional telephone qualitative interview** to find out what it was like being in the study.

What happens to my samples?

Your samples will be frozen and stored for further analyses relating to the study. We will use gene sequencing techniques to find out more information about the bacteria in your urine sample. Sometimes these techniques might pick up some of your own DNA, but our computer system automatically deletes any human DNA it detects and does not analyse this. The samples will be stored anonymously and further biochemical and microbiological tests related to urine infection or the way in which D-mannose works may be performed on them.

There will be additional optional consent for the use of your samples in other studies. If you consent to this we may share your anonymous sample with commercial companies working in the UK, Europe or the USA who are trying to develop better tests for urinary tract infection.

Pros and cons of taking part.

You may not experience any direct benefits by taking part. There is a slight chance you might experience diarrhoea as a previous study showed that 8 in 100 women experienced this, but still felt they were able to continue taking D-mannose.

However, we hope this study will benefit future patients who have recurrent UTIs if we can show definitively whether D-mannose helps to reduce UTI episodes or symptoms.

The requests we make when you agree to take part in the study are:



Taking the powder every day: this is important so we can be sure that results are due to study product or placebo and not because powder wasn't taken regularly.



Being in regular contact with us as described under 'follow up' on the previous page.

What if there are any problems?

If there is a problem or you have any concerns, you can contact the study coordinator (details on last page).

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment with which you are provided.

If you want to make a complaint.

If you wish to complain about any aspect of the way in which you have been approached or treated in this study, you should contact the Trial Team, tel: 01865 617827, email: merit@phc.ox.ac.uk or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or the head of CTRG on ctr@g@admin.ox.ac.uk

More information about taking part.

Do I have to take part?

No, taking part is entirely voluntary and will not affect your current or future NHS treatment.

What happens if I change my mind?

You are free to change your mind at any time during the study, but unless you state otherwise, any data or samples which have been collected whilst you have been in the study will be used for research as detailed in this participant information sheet.

If you were to lose your capacity (ability to give permission) during the study we would use information and samples you have already provided but not collect further information or samples. Once your data has been anonymised and combined with others' it will not be possible to withdraw it from the study.

Will I be reimbursed for taking part?

We will send you a £10 gift voucher after every two months study participation - a total of three vouchers - to thank you for your time.

Will my taking part in this study be kept confidential?

Yes. You will be given a study number. Any information you provide will be recorded against that number, not your name. Therefore all information is anonymous, as is any data we collect from your medical records.

All the study data is owned by the University of Oxford. It will be kept locked away or on secure computer servers in locked rooms with restricted access. Anonymised data may be shared with other researchers for research purposes.

Responsible members of the University of Oxford and the relevant GP practice may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations. We will be using information from you and your medical records in order to undertake this study. Research is a task that we perform in the public interest. The University of Oxford, as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible. We will keep identifiable information about you for three months after the study has finished, unless you consent to be contacted for future research in which case we keep your details for five years, stored separately from the study data on a secure university computer in the Department of Primary Care, Oxford University. We will store the anonymised research data and any research documents with personal information, such as consent forms, securely at the University of Oxford for five years after the end of the study.

Your GP will be informed that you are taking part in this study by post or email, and provided with a copy of your signed consent form

We will keep identifiable information about you for three months after the study has finished, unless you consent to being contacted for future research in which case we keep your details for five years, stored separately from the study date on a secure university computer in the Department of Primary Care, Oxford University. We will store the anonymised research data and any research documents with personal information, such as consent forms, securely at the University of Oxford for five years after the end of the study.

What will happen to the results of the study?

We will combine data from all the study participants, including your data, and publish the findings in journals and at conferences. You would not be identified from any report or publication placed in the public domain. You can visit our website on www.phctrials.ox.ac.uk/studies/merit; contact us for the results on merit@phc.ox.ac.uk or 01865 617827; or you can pick up a copy of the summary from your GP practice (after June 2021).




Talk to us!

If you want to discuss the study, please contact the MERIT team at merit@phc.ox.ac.uk; return your contact sheet using the pre-paid envelope provided or go to this webpage: www.phctrials.ox.ac.uk/studies/merit

If you would like to discuss the study with somebody else, you can also talk to your GP.

What should you do next if you are interested in taking part?

You can either:

-  Complete your contact details on the contact sheet attached and send it back in pre-paid envelope, or
-  Go to <https://sentry.phc.ox.ac.uk/merit-live-eoi> and complete your details online, or
-  Contact the study team directly on 01865 617827 or merit@phc.ox.ac.uk

