

## CLASS

Chlamydia Screening Study

### Chlamydia Screening Study 2

Thank you for taking part in the first part of this research. We are now inviting you to take part in a study of the management of Chlamydial infection, also funded by the National Health Service. This leaflet explains why the research is being done and what it will involve. Please take time to read the following information, which will help you decide whether or not you wish to take part. Please ask us if there is anything that is not clear.

#### Why are we doing this study?

Chlamydia is an infection that is passed from person to person, usually through sexual intercourse, and can be cured with antibiotics. We are doing this study to find out how best to manage people with Chlamydia and their sexual partners. The National Health Service is funding this research to help to decide whether or not a national screening programme is needed to reduce the problems caused by Chlamydia in the country.

#### Why have I been chosen?

The test that you did at home shows that you have a Chlamydia infection that needs to be treated. We would like all people with a positive Chlamydia test to take part in this study in order to get information about the best management for a wide range of people. Altogether, about 500 people in Bristol and the West Midlands have been asked to take part in this study.

#### Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you will be asked to sign a consent form. You are still free to withdraw from the study at any time without giving a reason and this will not affect the standard of care you receive.

We need as many people as possible to take part so that the results can be used with confidence.

#### What will happen if I take part?

This study is a randomised trial comparing two ways of managing people with Chlamydia infection because we do not know whether this should be provided at a specialist genitourinary clinic or from your GP surgery. People will be put into groups using a computer to select the groups by chance. We can then compare the two groups, who should be alike in every respect, other than the management received. You have an equal chance of being in either group. You will be involved in the research for about six weeks. The flow chart shows (on the following page) what will happen if you take part.

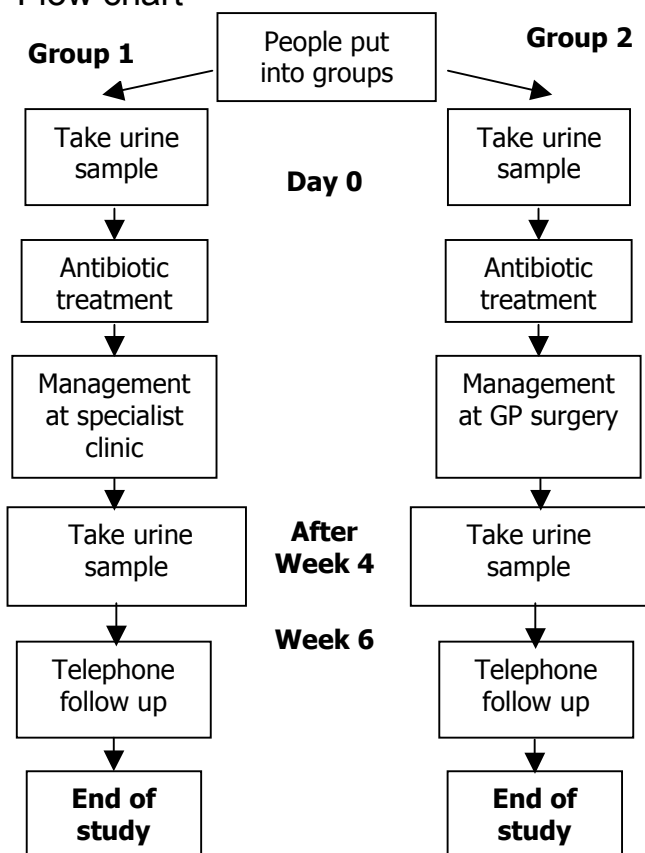
First, you will be asked to repeat the urine sample that you did at home to look at the accuracy of the test. Both groups will receive a one-off dose of antibiotics (azithromycin) to cure the Chlamydia infection.

One group will then be referred to the Milne Centre, Bristol Royal Infirmary, Bristol/Whittall Street Clinic, Birmingham, where investigations to identify any other infections will be performed by specialist doctors and nurses and specialist health advisers will help you to inform any sexual partners needing treatment.

The other group will receive further information and advice from the practice nurse about ensuring that sexual partners receive treatment.

After four weeks both groups will be asked to provide a further urine sample to check that the infection has gone. You can return the specimen in the Freepost envelope.

### Flow chart



Two weeks after that we will contact you by telephone to find out about your experience and what happened to any partner who needed treatment. About ten people from each group will be asked to take part in an interview that will ask about your experience and any problems you encountered during the research. We will reimburse you for any travel that you have to do as part of the study.

### What are the benefits of taking part?

You will receive free treatment for your Chlamydia infection and we hope that both methods of management will benefit you. We hope that you will agree to take part. The results of this study are of national importance in helping to manage people with Chlamydia better in the future.

### What are the disadvantages of taking part?

It is difficult to talk about sexual matters. Chlamydia is a sexually transmitted infection and getting a positive result may be upsetting to you. We advise you to consider carefully how you would feel about this before agreeing to take part. Sometimes there are consequences for sexual relationship(s) now or in the past but we will ensure that you receive the advice and support that you need.

Azithromycin is an antibiotic that may cause side effects, most commonly mild stomach upset.

### Confidentiality

All information collected about you during the course of the study will be kept strictly confidential. Your name and your address will be removed from any information outside your GP surgery. You will not be identifiable in any published report from the study. Ethical approval for this study has been obtained from 'South and West Multicentre Research Ethics Committee'

### Contact details

If you need any further information, please contact: Anne McCarthy, Project Manager, Department of Social Medicine, University of Bristol, Bristol, BS8 2PR. Tel: 0117 928 7275 or Dr. Aisha Holloway, Assistant Project Manager, Department of Primary Care, Birmingham. Tel: 0121 414 2282 or Freephone 0800 975 9985

