Brighton and Sussex University Hospitals NHS Trust

Brighton 3 in 1 Study in MSM

INFORMATION ABOUT THE RESEARCH

We would like to invite you to take part in a research study.
Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to your doctor or nurse about the study if you wish.

Why is this study being carried out?
We would routinely test you for chlamydia and gonorrhoea in a urine sample and in swabs taken from the throat and rectum (bum) if you tell us that you have had oral and anal sex. This is a maximum of 3 separate tests. We want to know whether it is possible to combine the swabs we do from throat and rectum with the urine sample so that only one test rather than two or three, needs to be processed by the lab.

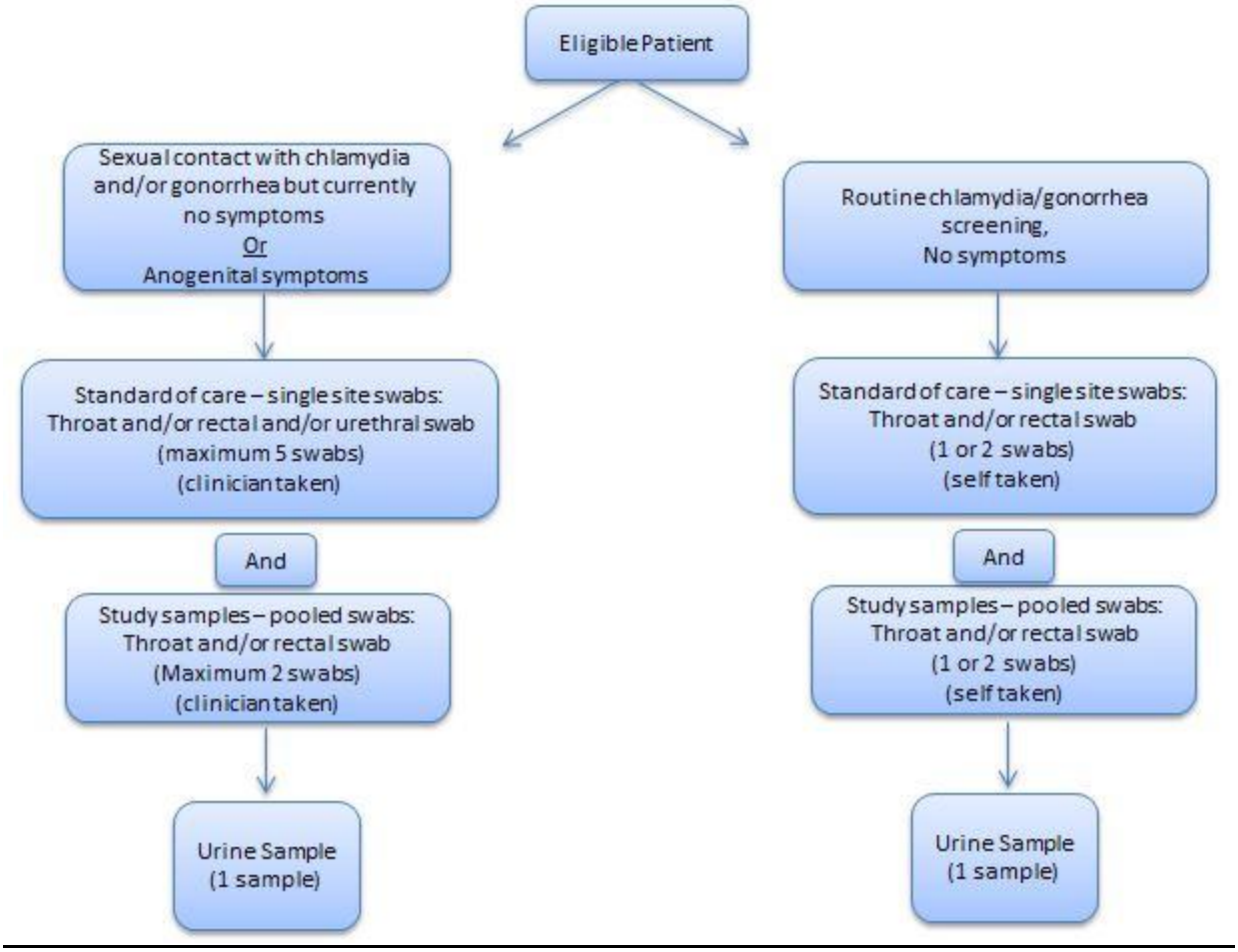
What are the benefits of the study?
There are no direct benefits from the study itself but if we find out that the 3 in 1 test is as good as the 3 separate tests, it is likely that we will be able to process tests quicker and get your result to you quicker.
This will also be cheaper saving the health service a significant amount of money.

Why have I been invited?
You have been invited to participate because we are studying men who have sex with other men aged over 16 years who are being tested for Chlamydia and gonorrhoea.

Do I have to take part?
No. It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part.

What will happen today if I take part?
As part of your routine care, you will be seen by a healthcare professional who will ask you some questions and then explain to you which tests need to be done and how. A nurse or doctor will take one swab each from the throat and back passage if you told us you have had oral or anal sex. In addition, you will take the same swabs again to be put together in one tube that we can add your urine sample to – these will be taken by you rather than the nurse/doctor and will be sent to the lab and tested together in one tube rather than separately. So in total you will have a minimum of 2 swabs taken and a maximum of 5. Following the samples being taken you will be asked to complete a short questionnaire asking you on your views on taking the swabs; this will take no longer than 10 minutes. If you decide to take part in this study, your clinic appointment may take an additional 20 minutes longer in total.

Figure 1: Patient pathway:



What will happen if any of my test results are positive?
As is normal practice, we would call you to tell you your result is positive within 2 weeks, and invite you to come back to clinic for antibiotic treatment.

What will happen if my test results are negative?
As is normal practice, you will be informed of your negative results by a text message received within 3 weeks after your clinic visit.

Will my taking part in the study be kept confidential?
Yes. If you consent to taking part in this study, relevant parts of your medical records may be seen by authorised members of the research team at your hospital, and representatives of the study sponsor and/or regulatory bodies only. All information will be kept strictly confidential.

We will also collect information from your notes but we will only record your clinic number. No names or addresses will be kept on the database and only the research team will have access to the data. From time to time other designated people may check the notes as part of regulatory processes and to check that the study is running correctly.

What happens if I don't want to take part?
If you decide not to participate it will not affect the care you will receive. If you have participated in the study and later decide that you want to withdraw, swabs already collected with consent would be kept and used in the study but no further research procedures would be carried out in relation to you.

I have some more questions about the study, who can I ask?
The team will be able to provide answers to any further questions you may have after reading this information leaflet and will be able to provide any support you need. You can also contact the main study researcher, Dr. Suneeta Soni, whose contact details are below.

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What if something goes wrong?
If you are not happy with any aspect of this research study, in the first instance please contact the research team. If you are not able to resolve your complaint, please then contact the Head of Research & Development (Scott Harfield, 01273 696955 ext 7497). If you still do not feel the issue has been resolved, the Complaints department at Brighton and Sussex University Hospital NHS Trust should be contacted (01273 696955 ext 4511 complaints@bsuh.nhs.uk).

Who is organising and funding the research study?
The research is being organised by Brighton and Sussex University Hospital NHS Trust. The study is being funded by Becton, Dickinson U.K. Limited

Thank you very much for taking time to read this leaflet.