UK Health Security Agency

Could DoxyPEP cause chlamydia to become antibiotic-resistant? Chlamydia AntiMicrobial Resistance Among DoxyPep users (CAMRAD)

Participant Information Sheet

We would like to invite you to take part in this research study. Before you decide, please read the following information carefully. It explains why the research is being done and what taking part will involve. Please ask a member of the clinic team if anything is unclear or if you would like more information. Taking part is completely voluntary.

What is the purpose of this study?

Chlamydia is a common sexually transmitted infection (STI). It is usually treated easily with doxycycline, a type of antibiotic. Unlike some infections, chlamydia has not shown antibiotic resistance in people to date. Antibiotic resistance means that bacteria stop responding to antibiotics that are normally used to treat them.

Doxycycline post-exposure prophylaxis (doxyPEP) is used by some people to reduce the chance of getting some STIs. Because doxyPEP means repeated doses of the antibiotic doxycycline, we would like to understand whether this could lead to reduced antibiotic effectiveness, or early signs of doxycycline resistance in chlamydia. Taking part in this research will **not** affect your care.

Why have I been asked to participate?

We have asked you to take part in this study because:

- you are aged 18 years or older,
- You are one of the following people having sex with men:
  - Transgender women
  - Non-binary person
  - Cisgender or transgender men
- you are being tested for chlamydia or have already been diagnosed with chlamydia, and,
- you may be using doxyPEP.

Do I have to take part?

No. Taking part is completely optional and voluntary. If you decide to take part, the clinician will document your verbal consent in your clinical record. You are free to decline without giving a reason. Any decision you take will not affect the care you receive.

What will be involved if I take part in this study?

If you agree:

1. One or more additional swabs from the penis, throat, and/or rectum will be collected by yourself or by the doctor or nurse. These samples will then be sent to the UK Health Security Agency (UKHSA), where they will try to grow the chlamydia bacteria.
2. We will ask for some information about you such as your age, gender, sexual orientation and whether (and how) you use doxyPEP. We will not ask for any information that would allow us to work out who you are (also called identifiable data).
3. The collected samples will be pseudonymised. This means we will label your sample with a unique ID number (rather than using any of your identifiable information). However, this also means that in cases where the identity of your sample is required for clinical reasons it could theoretically be relinked. This will allow us to discard your sample if you are no longer eligible to take part in the study. We will not be able to identify who you are from your sample.
4. If your routine test is **negative for chlamydia** (i.e., you do not have chlamydia), the research sample and any collected data will be safely discarded. If your routine test is **positive for chlamydia** (i.e., you have chlamydia), the research sample will undergo testing at UKHSA.

5. If chlamydia is successfully grown from your sample, further tests will be carried out:
    - laboratory tests to check antibiotic susceptibility. This means testing how well different antibiotics kill the bacteria.
    - Analysis of the genetic material of the bacteria to look for signs that the bacteria might be developing resistance to antibiotics.

What are the advantages/benefits and disadvantages/risks of taking part?

You will not need to return for any extra visits relating to this study, and the study will not affect your treatment or results. Taking part requires only a few extra minutes today for the additional sample(s) and answering a few questions. There are no known risks beyond those associated with routine swabs (possible brief discomfort if a rectal sample is provided).

There is no direct benefit to you, but your participation will help improve understanding of antibiotic resistance and support safe use of doxyPEP in the future. The results from the additional research tests will not be given to your treating clinician, and they will not be shared with you. This is because these research tests take many weeks to complete, and by the time the results are ready you will already have been treated. In addition, some of the tests, such as measuring antibiotic susceptibility or looking at genetic markers of resistance, are still being evaluated, and we do not yet know how well these results relate to treatment outcomes in real life. For this reason, the information from these tests cannot be used to guide your clinical care. No payments or expenses are offered.

Can I withdraw from the study at any time?

Yes. You can withdraw at any time **while your sample is still in the clinic**. You can tell a member of clinic staff during a clinic visit, by telephone, by email, or through another usual method of contacting the clinic. Withdrawing will **not** affect your clinical care.

If you withdraw:

- No further samples will be collected.
- Any sample still in the clinic and not yet sent will be destroyed.
- No further study data will be collected. Once your sample has been transferred to UKHSA and processed for the laboratory testing described in this study, it will no longer be possible to withdraw that sample or any data generated from it, as it will already have been used for the study analyses.

Any data or test results already generated before your withdrawal may still be used, if you agreed to this as part of the consent process.

Who is doing the study?

This study is being led by researchers in the National Institute for Health and Care Research Health Protection Research Unit in Blood Borne and Sexually Transmitted Infections at UKHSA (an executive agency of Department of Health and Social Care) in partnership with University College London. Laboratory work will be carried out at the UKHSA Sexually Transmitted Infections Reference Laboratory in London. The clinics taking part in this study are sexual health services in England. No commercial organisation is funding or involved in the study.

How will we use information about you?

In this research study we will use information from you and your medical records. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will only use information that we need for the research study.

We will need to use information from your medical records for this research project. This information will include your:

- Age range
- Gender identity and sexual orientation
- Sex assigned at birth
- Ethnicity
- Date of sample collection
- Presence or absence of symptoms
- Site(s) of sample collection
- Use doxyPEP, and timing of last dose and frequency of doxyPEP use
- Any other systemic antibiotic use in the last three months

We will use this information to do the research. We do not need to know who you are and will not be able to see your name or contact details. Your data will have a unique code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data in order to interpret the results of our study. We will make sure no-one can work out who you are from the reports we write.

UKHSA is the sponsor of this research and sole data controller. UKHSA is responsible for looking after your information. We will not share your information related to this research project with any other organisations

We will keep all information about you safe and secure by:

- The use of the pseudonymised unique ID number
- No identifiable information will be transferred to UKHSA, only the pseudonymised unique ID number will be used
- Data will be transferred from the participating clinic to UKHSA via the secure Snap Survey platform.
- All data processing and analysis will be conducted on secure UKHSA servers with restricted access.

Your data will not be shared outside the UK.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason. If you withdraw while your sample is still in the clinic, it will be destroyed and no further information will be collected. Once your sample has been sent to UKHSA, it cannot be withdrawn because it cannot be linked back to you. Any information or results already produced before you withdraw may still be used, but only if you agreed to this during consent. We need to manage your records in specific ways for the research to be reliable, which means that we won't be able to let you see or change the data we hold about you.

How will we use information about you after the study ends?

If you consent, this will be recorded in your sexual health record. These records are subject to specific retention requirements by the NHS. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will keep your study data for a maximum of 10 years and will then be securely destroyed.

What will happen to the results of the study?

The results of the study will be presented at scientific meetings and published "open access" in medical journals. This means you will be able to access the results through these journals as "open access" means they are free for all to access. We will also share the study findings

with participating clinics, and a summary will be provided on HPRU BBSTI website (https://bbsti.hpru.nihr.ac.uk/research). You will not be identified in any report or publication.

Who has reviewed this study?

This study has been approved by London – Bloomsbury Research Ethics Committee (26/LO/0336).

Who do I contact if I have a concern about the study or I wish to complain?

If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, you may have grounds for legal action, but you may have to pay for it. Regardless of this, if you have concerns about any aspect of the way you have been approached or treated during the course of this study you may wish to contact your local Patient Advice and Liaison Service (PALS) whose details can be given to you by any members of the clinic staff or by going to this link: https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/

If you have a concern about any aspect of this study, please speak to Dr Sarah Alexander (STIlab@ukhsa.gov.uk), and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact:

UKHSA Complaints Team, 10 South Colonnade, London E14 4PU. Alternatively, you can e-mail complaints@ukhsa.gov.uk

Further information on the complaints procedure can be found at: https://www.gov.uk/government/organisations/uk-health-security-agency/about/complaints-procedure

If you agree to take part, would like more information or have any questions or concerns about the study please contact, The STI Reference Laboratory at UKHSA: STIlab@ukhsa.gov.uk.

Where can you find out more about how your information is used?

For more information about how UKHSA handles personal data, you can read our privacy notice: https://www.gov.uk/government/publications/ukhsa-privacy-notice/ukhsa-privacy-notice

Thank you for taking the time to read this information sheet.