Contact HPOS team at: hpos@ndorms.ox.ac.uk

PARTICIPANT INFORMATION SHEET

Hippocrates Prospective Observational Study (HPOS)

We'd 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.

What is the purpose of the study?

The aim of this study is to try to understand why some people with psoriasis develop arthritis and some do not. We already know about some characteristics that increase the risk of developing arthritis. We want to investigate for other factors that may help us predict whether someone with psoriasis is likely to develop arthritis including facts about you, your lifestyle and your psoriasis treatment.

Why have I been invited?

You have been invited because you have psoriasis but have not yet developed arthritis. We are aiming to collect information from 25,000 people with psoriasis across many countries in Europe. You may have heard about the study from your doctor or you may have seen a link through a charity website or on social media.

Do I have to take part?

No. It is up to you to decide whether or not to join the study. This information sheet will explain the study to you. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive or any future treatment you may need.

What will happen to me if I decide to take part?

If you agree to participate, we will ask you to register online and complete a consent form to take part in the study. Because the study aims to collect information over a three-year period, we are aiming to make your involvement as simple and flexible as possible. When required we will contact you by email. You will be free to decide how much you want to take part and your preferences at any time during the study.

Once you have registered on the study website and we have received your consent, we will ask you to enter some details about you and your health onto the website. This will include

- Your height, weight and waist circumference
- Details about your psoriasis and how severe it is
- Details about other key medical conditions
- The treatment you are using for psoriasis
- Any arthritis symptoms that you have

We would also like to know how your symptoms and treatments change over time. These reminders will be to complete questionnaires and update your medical information and will be sent by e-mail.

We will also ask for your permission to access and use your NHS and social care records to get more information about you and the services you have accessed.

What should I consider?

This study will not change your treatment. If you have symptoms that may be caused by psoriatic arthritis, we will advise you to seek help from your doctor for an assessment.

Are there any possible disadvantages or risks from taking part?

This study has a low risk of harm. With the exception of sharing your details with other authorized research administrators whose research you have consented to, the secure and confidential parts of the website will only be accessible to those authorized individuals, yourself and our website administrator.

What are the possible benefits of taking part?

We cannot promise the study will help you personally, but we will use the information you give us to help develop new tests and treatments for psoriatic arthritis.

Will my taking part in the study be kept confidential?

Yes, we value your information and take security and confidentiality very seriously. The website is password protected, and you will be the only one aside from the authorized research administrator(s) that can access your secure area. Your personal information is stored and encrypted by the University of Oxford. It is available only to the authorized administrators so they can match your account with your information. If you consent to be approached in the future regarding other ethically approved research your personal details will be kept separate from your anonymised data and will only be accessed by an authorized research administrator. Agreeing to be contacted in the future does not oblige you to take part in any future research, you are only agreeing to be approached for possible inclusion in a study.

Any samples that are sent to us will have your name and address removed so that you cannot be identified. It will be stored in an anonymised form where, again, only the authorized study administrator(s) will be able to link the sample to the anonymised data. Your anonymised information will be held in a secure database, which is located at the University of Oxford.

Responsible members of the University of Oxford team may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

There should be no costs to taking part in this study and no reimbursement is available.

What will happen to the samples I give?

We will contact some participants to ask for a sample of blood. If you are selected, you will be posted a kit with everything you need to take the small blood sample at home. You will then post this back and the samples will be stored at University College Dublin, Ireland. To help keep your information confidential, your sample and any information recorded about you in this study will be 'de-identified' and assigned a study code. However, your DNA is unique to you so it can never be completely anonymous.

At the end of the study, the samples will be stored in Dublin, with consent, for future use. Your anonymised samples will be used mainly by HPOS researchers but may also be used in ethically approved research projects which may take place in hospitals, universities, non-profit institutions or commercial laboratories worldwide.

What will happen to my data?

UK Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford, based in the United Kingdom is the controller and is responsible for looking after your information and using it properly.

We will be using information from the online HPOS database and your medical records in order to undertake this study and will use the minimum personally identifiable information possible. We will keep identifiable information about you for 6 months after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely on the servers at the University of Oxford for 6 months after the end of the study. If you agree to your samples being used in future research, your consent form will be held until the samples have been depleted or destroyed.

UK Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting Professor Laura Coates or the HPOS study team at hpos@ndorms.ox.ac.uk Data collected about you during the study may be looked at by both national and international industry researchers. These researchers will first be approved by the HPOS Data Access Committee to ensure their involvement will help contribute to the aims and objectives of HPOS. The HPOS data access committee is a group of researchers overseeing this project whose role is to ensure that your data within this study is used for appropriate analysis. External academic and industry partners may apply to the data access committee to ask us to share the data allowing them to answer additional research questions.

What will happen if I don't want to carry on with the study?

You are free to withdraw from all or part of the study at any time. On your page of the website, you will be able to indicate which parts of the study you do not want to carry on with, and whether you want to withdraw samples and information that have already been collected, or simply stop any involvement in the future. It will not be possible to remove any information that has been anonymised and already used in research analysis.

If you die while taking part in the study, data and samples you have provided would continue to be available for use in the study, based on your choices recorded at the time of your death.

What will happen to the results of this study?

Results from the study will be presented in professional journals and at conferences. We will send you a newsletter every year to keep you informed of the study's key findings. You will not be able to be identified in the results.

What if we find something unexpected?

If the questionnaires in the study suggest that you may have psoriatic arthritis, we will inform you of this and advise you to seek medical help locally.

What if there is a problem?

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.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Prof Laura Coates on laura.coates@ndorms.ox.ac.uk or you may contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) office on 01865 616480, or the director of RGEA, email: rgea.complaints@admin.ox.ac.uk

How have patients and the public been involved in this study?

Patients with psoriasis and psoriatic arthritis have helped develop the research topic and what research questions should be asked and a team of patients will continue to be involved in the study. Potential participants were involved in reviewing the Participant Information Sheet. In designing this study, we have taken into account patient opinions on the frequency of questionnaires and the tests that we will carry out.

Who is organising and funding the study?

This study is funded by a European Innovative Medicines Initiative grant.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by London – City and East Research Ethics Committee.

Participation in future research:

We will also ask your permission for the study team to contact you if there are new studies for which you may be eligible. Agreeing to be contacted does not oblige you to participate in any studies and you can change your preferences on the website at any time to be removed from this list if you wish. If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database but will keep the consent form and your details separate.

Further information and contact details:

Please contact the study team by hpos@ndorms.ox.ac.uk

Thank you for reading this information.