PREVeNT RA:

A nationwide register of first-degree relatives of patients with rheumatoid arthritis to evaluate predictors of the development of rheumatoid arthritis

PARTICIPANT INFORMATION SHEET

PREVeNT RA
PRe-clinical EValuation of Novel Targets in RA

Contents:

Why we are doing this study	1
Why am I being asked to take part?	2
What will I need to do if I take part?	3
What else will happen if I take part?	4
Do I have to take part?	5
What are the possible benefits and risks of taking	6
How will the information collected be kept confidential?	7
What if there is a problem?	8
Who is organizing and funding the research?	9
Who has reviewed this study?	10

How to Contact Us:

If you have questions about this study, please contact:

PREVeNT RA

Arthritis Research UK Centre for Epidemiology
Centre for Musculoskeletal Research
Institute of Inflammation and Repair
Stopford Building
The University of Manchester
Oxford Road
Manchester
M13 9PT

Call: **0161 275 5504**

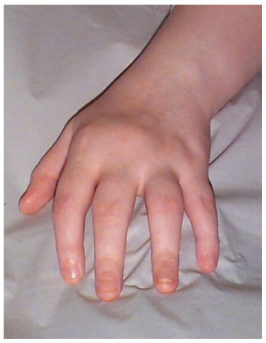
Email: preventra@manchester.ac.uk

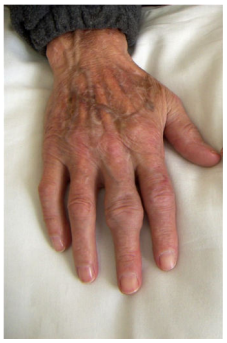
We invite you to take part in a research study

- Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide whether or not you wish to take part.
- You are free to decide whether or not to take part in this research study. If you choose not to take part, this will not affect the care you get from your own doctors.
- Ask us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information. If you decide to take part you will be given a copy of this information sheet and your signed consent form.

Important things you need to know

- The purpose of the study is to identify risk factors for developing rheumatoid arthritis by studying people who are first degree relatives of someone with rheumatoid arthritis, but do not themselves have rheumatoid arthritis.
- Rheumatoid arthritis is a condition where joints and other parts of the body become inflamed. This can cause damage to cartilage, bones, tendons and can lead to complications in other organs in the body. Below are pictures showing how rheumatoid arthritis may affect a person's hands.





Rheumatoid arthritis of the hand. Left to right: Severe rheumatoid arthritis affecting the hands

- We will look at genetic, environmental and other factors to understand what makes people more likely or less likely to develop rheumatoid arthritis.
- Once we have found ways to identify those with a high likelihood of developing rheumatoid arthritis we hope to design trials aimed at preventing the disease.

1. Why we are doing this study

The purpose of the study is to understand risk factors for developing rheumatoid arthritis. This is being done by studying individuals who are currently well but who are first degree relatives (i.e. is a parent, child, brother or sister) of someone with rheumatoid arthritis.

We will look at a number of factors for each person - including their genes, the immune system and the lifestyle environment to understand what makes people more likely or less likely to develop rheumatoid arthritis.

This study will help us to develop interventions for preventing rheumatoid arthritis, which we then aim to test in future randomised studies.

2. Why am I being asked to take part?

The reason why you have been asked to take part in this study is because you have a parent, child or sibling who has rheumatoid arthritis.

We are interested in how our genes, our environment and other factors lead to some people developing rheumatoid arthritis while other people do not.

Examining what the risk factors for developing rheumatoid arthritis are will provide information on how this process occurs and how it is influenced. This will help us to develop interventions for preventing the disease in the future.

3. What will I need to do if I take part?

If you decide to take part, there would be no change whatsoever in the normal healthcare treatment that you receive. We would ask you to complete a questionnaire about your family history, lifestyle, pain and wellbeing. We will request your permission to take a blood sample from a vein in your arm for research purposes.

Depending on where you live, we would send you a blood sample collection kit, which you can take to your GP practice or local clinic for them to take your blood and return to us. Alternatively, we would invite you to a clinic or another convenient location to have your blood sample taken. If you are unable to obtain a blood sample for any reason, we would ask you to consider allowing us to collect a sample of saliva instead.

4. What else will happen if I take part?

Your blood sample and questionnaire responses will be considered a gift to The University of Manchester. These will be processed, stored and remain the responsibility of The University of Manchester. The University of Manchester now stores blood samples at a specialist company, UK Biostores and Services Ltd. in Trafford Park, Manchester, with whom it has a contract in place. From the blood we will extract and store samples of serum, plasma, and genetic material, which we will then be tested to answer our research questions. With your permission parts of these stored samples may later be passed to other partner laboratories for similar tests.

With your agreement we would inform your GP about you taking part in this study. We would also ask for your agreement to be contacted in the future with information about future clinical trials and studies.

We would ask for your permission to link your study record with relevant parts of your health records that are held by the NHS and other national databases. We would also ask for your agreement for data collected during the study to be looked at by responsible people from the university of Manchester. We may also contact you to request that you complete follow up questionnaires to see if you have developed joint pain.

Some participants will be invited to take part in sub-studies or complete additional questionnaires linked with this main study. You would have the opportunity to decide whether on not to take part, and would be given separate consent forms and information leaflets for these.

If in the future you notice symptoms of joint pain and stiffness, we would ask you to let us know about these symptoms. We would also ask you to see your GP as soon as possible so that they can refer you to see a rheumatologist. You will be followed-up in the rheumatology clinic according to best practice and depending on your health at the time. If you develop symptoms of joint pain and/or stiffness, we may also invite you to attend a research clinic. We may ask for your permission to undertake an ultrasound scan of your joints. The scan is carried out using an ultrasound probe and does not involve any needles. The scan is not painful and does not involve any discomfort. This non-invasive procedure will give valuable information about any inflammation in your joints, and may be helpful in developing better treatment in the future for patients with early inflammatory arthritis.

5. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at anytime and without giving a reason. This will not affect the standard of care you receive. If you withdraw from the study, we will destroy all of your identifiable samples, but we will need to use the data collected up until the time of your withdrawal.

6. What are the possible benefits and risks of taking

There would be no clinical benefit directly to you for taking part in this study. As this is a study involving the examination of the patterns of large numbers of individuals, no results on your own genes will be fed back to you. However, better understanding of the mechanisms that lead to joint inflammation may allow the development of new treatments, thus may be of benefit to patients in the future. The results of these studies are likely to be published in medical journals and you would be most welcome to obtain a copy of the published research. Additionally, we will periodically send you updates about our research findings in the form of a participant newsletter.

Taking a blood sample can sometimes result in bruising and discomfort around the needle entry site.

7. How will the information collected be kept confidential?

The results of the research will be stored using study numbers so that your name will not be available to anyone other than the researchers involved. The computers being used to store your results are located at The University of Manchester and are password protected. The data files regarding the study are also encrypted and password-protected.

8. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance Co-ordinator on 0161 2757583 or 0161 2758093 or by email to research-governance@manchester.ac.uk.

You can also talk to the NHS Patient Advice and Liaison Service staff (PALS), who may be able to resolve your concerns or can provide you with the details of how to make an official complaint.

In the event that something does go wrong and you are harmed or suffer loss as a result of taking part in the research you may have grounds for claiming compensation from the NHS or the University of Manchester, but you may have to pay legal costs. The normal NHS complaints mechanisms will still be available to you.

In order to protect you, the University Manchester has insurance in place.

9. Who is organizing and funding the research?

This research is funded jointly by the UK Medical Research Council, the Association of the British Pharmaceutical Industries, and the National Institute of Health Research.

It is important for you to understand that the use of your sample/s may have commercial value and the results generated may be of valuable intellectual property. If you decide to participate in these studies you agree to give your sample/s to the researchers who will be free to use your sample/s for academic and/or commercial research related to the cause and treatment of arthritis. You will not own the results generated using your sample/s.

10. Who has reviewed this study?

This study has been reviewed by the Greater Manchester West Research Ethics Committee.

Thank you for considering taking part in this study!

Contact for Further Information

Changes due to COVID-19:

The PREVeNT RA study team are mainly working from home due to the COVID-19 situation, however will be on campus a couple of days per week. Post and phone messages can be picked up then, however we would urge participants to contact by email for a faster response at:
preventra@manchester.ac.uk

Please note that when you are sent a blood sample kit, you will be given details on contacting sites or your GP with the kit. When you contact a hospital site or GP for an appointment you will be given advice and instructions with regards to safety relating to COVID-19 at their specific site.

Division of Musculoskeletal and Dermatological Sciences | The University of Manchester |
2nd Floor Stopford Building | Oxford Road | Manchester | M13 9PT
Email: preventra@manchester.ac.uk
Call: 0161 275 5504