

Autoimmunity Relapse Prediction using Multiple Parallel Data Sources

Patient information Sheet for patients with systemic vasculitis Version 2_May 2018

You are being invited to take part in a research study. This information sheet will help you understand why we are doing the research and what we would like you to do. Please read the sheet carefully and feel free to discuss it with others if you wish. Please ask us if there is anything that is not clear to you or if you would like more information. Please take as much time as you need to decide whether you wish to take part or not. Further detailed information regarding how we will use your data is available here: https://www.tcd.ie/medicine/thkc/assets/pdf/Data%20Management%20Plan_v1.1.pdf. Thank you for reading this.

What is the purpose of the study?

This study will investigate whether things that you meet in your environment can trigger a flare of vasculitis. For example, vasculitis may be more common in the winter. We will try to find out whether various infections (such as flu), pollution or a change in the weather trigger the disease.

Why have I been invited?

You have been invited because you have a vasculitis condition. We hope to understand the disease affecting you and others more clearly.

Do I have to take part?

NO. It is entirely up to you to decide whether or not to take part. If you do decide to, you will be given this information sheet to keep and we will ask you to provide your consent. If you decide to take part, you are still free to withdraw at any time and you do not need to give a reason if you so wish. A decision not to take part, or to withdraw at any time, will in no way affect the standard of clinical care you receive.

What would the research involve for me?

We get most of the information for the study from the **patientMpower vasculitis support smartphone app** and from the information held within the **Rare Kidney Disease (RKD) registry**. When you download this app, you will be asked for your consent to two parts of the study:

1. **Use of your data.** This comes from two sources:
 - *Use of information provided by the app itself.* This includes your activity levels, location and current symptoms. We ask you to complete a quality of life questionnaire as often as you wish (but at least once per month). This has 5 questions and takes about 20 seconds to complete. The app also allows you to record pictures of, for example, a rash or swollen joint, and to record other

symptoms such as cough, fatigue or pain, which you can do as often as you wish. Your permission will be sought (through the app) for access to your activity levels (step count, as recorded by your smartphone) and GPS location. We are aware that providing location data is potentially sensitive from a privacy perspective; the ways in which we safeguard this information are detailed below. It is important that we collect these data as it allows us to link vasculitis flare events to the weather and pollution information from that time and place.

2. *Use of information from your record in the RKD registry.* This provides information about the status of your vasculitis, such as whether you have experienced a flare or not.

If you do not have a smartphone, or do not wish to use one, a member of the research team will contact you every couple of weeks to ask a series of questions about how you have felt.

We will also ask your permission to contact you if there are new studies for which you may be eligible. You are under no obligation to participate and you would need to provide formal consent to participate in any of these subsequent studies.

What data will we be using?

To perform the research, we will store and use two basic forms of data:

1. *Information obtained from your use of the app.*
 - a. We are mainly interested in how you feel and what symptoms you have over time.
 - b. GPS location over time.
 - c. Step count per day.
2. *Information from data stored in the registry.* This includes information relating to the type of vasculitis you have, the treatment you have received, hospital test results and how active your vasculitis has been over time. The main reason for this is to identify proven vasculitis flare events.

If you suffer a vasculitis flare, we will analyse local weather, pollution and infection information in the weeks leading up to the flare, using the GPS location to ensure that the data we use is accurate to where you were at the time.

In addition, we need to maintain a log of people who have been recruited, which includes *identifiable information*, such as name, date of birth and hospital number. This log will be held in a secure place separate from the research information described above, which will be coded, preventing researchers using the data from knowing who you are. As it will take a long time to observe enough flare events for analysis, we shall retain your data for 15 years. Trinity College Dublin is the data controller for this study. If you wish to complain

about use of your data, or require further information, please contact the data protection office on dataprotection@tcd.ie. If you wish to obtain a copy of your data, or if you feel that the data held is inaccurate, please contact the Study Coordinator on 085-150-7587, rkdnurse@tcd.ie.

Who will be using the data?

The AVERT research team will be the primary users of your data. This comprises a carefully vetted list of individuals in Trinity College or collaborating academic institutions. Apart from the custodian of the recruitment log, they will not be able to identify you directly, as detailed below. We may also share your de-identified data with external parties, including commercial entities, for use in studies that have received formal approval by a research ethics committee. If the results look promising your data may be incorporated into software that may be developed commercially into clinical support tools. Such sharing of data will be carefully defined and controlled according to a published data sharing agreement (www.tcd.ie/medicine/thkc/assets/pdf/Data-sharing-plan-v1.pdf).

Will my taking part in this study be kept confidential?

Yes. We have invested a lot of effort in ensuring that all information collected about you during the research will be kept strictly confidential. The study has been reviewed by the Data Protection Officer in Trinity College. Any information about you which is passed on to other researchers or published will be de-identified so that no one can identify you from the available information. Your name or address will not be published or passed on in any way.

The research data described above will be held in an approved “safe haven”, which means that very strict security measures are in place, with careful vetting of those individuals with access. We will use advanced data protection methods to protect electronic information about you. These data will be coded, which means that your name, location data or other identifiable information is not used.

However, your personal details and medical record number will be recorded on the research log which will allow us, with your consent, to link your information with information from other relevant studies you may have participated in, in particular the RKD registry. This log will be kept securely in a separate place to the coded research data. Access to these identifiable data will be strictly controlled in accordance with the **data management plan**, which describes in detail how we handle all the data in this study (https://www.tcd.ie/medicine/thkc/assets/pdf/Data%20Management%20Plan_v1.1.pdf). Responsible members of Trinity College Dublin 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 taking part have any negative effects on my health?

No. No additional procedures that may impact on your health will be undertaken.

Do I have to alter my lifestyle to take part?

No. We are interested in learning about relapse of vasculitis as you go about your normal activities.

What will happen to the results of the study?

If we find things out that are felt to be interesting by researchers from other hospitals and universities, the results may be published in a scientific journal. If this happens, no one will be able to identify you as having taken part in the research as, firstly, data will be de-identified and, secondly, results will be aggregated. We will also make available to you a summary of the study results via our website and by newsletter.

Who is organising and funding the research?

The research is being organised by Professor Mark Little, the Principal Investigator at Trinity College Dublin, in collaboration with experts in statistics and computer science. No individual taking part in this study is getting paid extra for including you in the study. Funding for the study comes from the Health Research Board.

Is there any payment for taking part?

No, we are not paying patients to take part in the study. However, there is the opportunity to be reimbursed for travel expenses for any additional clinic visits you make (visits that you would not have made for your routine clinical care).

Who has reviewed this study?

The Tallaght-St James's Hospital ethics committee has approved this study

Can I withdraw from this study if I change my mind about taking part?

Yes, you can withdraw from either or both parts of the study (use of app data and linkage to registry data). Please contact Professor Mark Little on 01-896-2145, mlittle@tcd.ie or the Study Coordinator on 085-150-7587, rkd nurse@tcd.ie. If you withdraw from the study, the information that we have obtained up to the point of you coming out of the study will continue to be used for the purpose of the study. If your data have already been used at the time you withdraw, it may be impossible to withdraw the results once they have been compiled with the results of others participating in the study, or if they have contributed to a published paper.

Exercising my legal rights

You have various rights under Irish data protection law, in addition to the choices we have laid out for you:

- You may ask to see a copy of the information we hold about you (except where it is de-identified)
- You may ask for a 'portable' copy of any data which you have provided
- You may object to any further processing of the information we hold about you (except where it is de-identified)

If you wish to exercise any of these rights, then please contact us through email, telephone or in writing as detailed below. In some circumstances, we may need to seek proof of identity and/or make a charge as permitted under data protection law.

Who should I contact about enquiries or complaints?

If you have any concerns or complaints about any aspect of the way you have been approached or treated during this study, you should contact Professor Mark Little on 01-896-2145 or the St James's Hospital CRF governance unit 01 410 3906 or dataprotection@stjames.ie.

Thank you for reading this information sheet.

If you wish to have further information about the study, please contact Professor Mark Little, Consultant Nephrologist or the AVERT Study Coordinator at:

Wellcome Trust/HRB Clinical Research Facility
St James's Hospital
Dublin D08 W9RT
Telephone: 085-150-7587