University of Exeter

NHS
Royal Devon University Healthcare
NHS Foundation Trust

StartRight

Getting the right classification and treatment from diagnosis of diabetes

Study Extension Phase

Data Collection & Feedback
For StartRight Participants Who Have:

- **Completed study follow-up & sample collection**
- **Received the C-peptide report from their final sample collection**

- **Please take the time to read the following information carefully.**
- **You are free to decide if you want to continue with this research study.**
- **You can decide to stop taking part in the study at any time without giving a reason.**
- **Please ask us if anything is not clear or if you would like more information.**

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This Research Project Is Funded By

The National Institute for Health & Care Research (NIHR) and Diabetes UK

Additional funding for this extension phase is provided by JDRF UK

1. Why are we doing this study extension?

Following your last StartRight study visit, at least 3 years after you joined the study, we sent you and your doctor the result of the C-peptide test on samples collected at that fvisit. As explained in the letter you received with your result, the C-peptide test tells us how much insulin your body is producing which, in some cases, may help to inform the most beneficial treatment of your diabetes. We would now like to update the information we have about your diabetes & treatment, to see if there have been any changes, and ask you to repeat the questionnaires about your glucose control and well-being.

In this extension we will assess the changes that occur in diagnosis, management and wellbeing after feedback of a C-peptide result, and participants' views on C-peptide testing, to help inform whether this approach is likely to be helpful for people living with diabetes in the future.

Routine C-peptide testing has already been adopted by a number of NHS hospitals, and gaining a greater understanding of the impact of this approach will help inform whether this should be adopted more widely, to identify people whose diabetes has been misclassified

2. Why have I been invited to take part?

We are inviting you because you have completed StartRight follow-up and sample collection and have received a C-peptide result from the samples collected at your last study visit.

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

Taking part will involve 10-15 minutes of your time to complete online questionnnaires* about your diabetes . As in previous study visits, we will ask questions about your diabetes, the treatment and management of your diabetes and your well-being. We will also ask for your feedback on taking part in the StartRight study and the results you received. Everything can be completed online*. **You will not be required to attend the hospital and you will not be asked to provide any samples.**

*If you do not have access to a computer, or would prefer not to complete the study extension online, we can arrange for it to be completed by phone interview with one of our researchers.

Your continued participation is entirely voluntary. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect your standard of care.

4. Who can I contact for further information ?

If you have any questions or concerns about this study, please contact the study team:

Email: **rduh.diabetesresearch@nhs.net**

What happens if I have a complaint ?

We would not expect you to suffer any harm from your continued participation in this study. However, if you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint with the Royal Devon University Healthcare NHS Foundation Trust who are the study sponsor. Details about this are available from the research team. Also, as a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. More information can be found on the NHS England website: **(https://www.england.nhs.uk/contact-us/complaint/complaining-to-nhse/).**
Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action.

5. Are there any risks or benefits in taking part?

This study extension involves providing information about your diabetes and treatment and completing some questionnaires, therefore no risks are anticipated.

Any information about changes to diabetes management, particularly if associated with improvements in glucose control or wellbeing would support routine C-peptide testing in people with diabetes requiring early treatment with insulin and help inform guidelines. Your feedback on taking part in the StartRight study will help to improve the way we design and carry out research studies in the future.

6. Who is organising this study?

This project is centrally coordinated by The National Institute for Health and Care Research (NIHR) Exeter Clinical Research Facility, a partnership between the University of Exeter Medical School and Royal Devon University Healthcare NHS Foundation Trust. The project is funded by the NIHR (the research arm of the NHS) and Diabetes UK (the leading UK charity for people affected by diabetes) with additional funding from JDRF UK (the Type 1 diabetes charity) for this extension phase. The project has been reviewed by the Peninsula Research Bank PPI group at the Exeter CRF and approved by the National Research Ethics Committee (South West-Cornwall & Plymouth) under IRAS reference number 203567. The study Sponsor is the Royal Devon University Healthcare NHS Foundation Trust.

7. How will we use your information?

In this research study we will need to use information from you, from your medical records and from your clinical care team for this research project. This information will include your NHS number, your name, your date of birth and your contact details which will be shared with the Chief Investigator's central study team in Exeter. People will use this information to do the research or to check your records to make sure that the research is being done properly. 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 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.

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, but we will keep information about you that we already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records & your clinical care team. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

You can find out more about how we use your information at **www.hra.nhs.uk/information-about-patients/** or by asking one of the research team (see section 10 for contact details).

8. What will happen to the data after the study has ended ?

When you joined the Startright study, you were given the option to donate the data collected for this extension phase to a research bank to be used in future research. This research bank is based in Exeter and is managed by a steering committee of healthcare professionals, academics, and members of the public who have also participated in research. The committee will ensure that samples and data are used anonymously on studies that they feel are ethically appropriate.

9. What will happen to the results of this study ?

We have previously sent you StartRight study updates including information about progress and summary results. We will provide summary results to all participants when the study is completed. Some of the results of the StartRight study are already published and you can access information about those results via our website **https://www.diabetesgenes.org/current-research/startright/**

Our reports and publications are written in a way to ensure that no-one can work out that you took part in the study.

10. What did I agree to when I joined the StartRight study?

If you decide to complete the study extension, your original consent to take part in the StartRight study will continue to apply. We have included those consent statements below for you to review:

I confirm that :

- I have been given a study information leaflet.
- I have had the opportunity to ask questions and have had these answered satisfactorily.

I am happy to:

- donate blood and urine samples collected during this study, and for DNA to be extracted from my blood sample.
- allow samples leftover from my routine clinical care to be used for diabetes research tests.
- provide information about my diabetes and other information relevant to my participation in the study.
- allow the research team to contact my clinician/GP about my participation in the study and to provide them with clinical results relevant to my care, including tests for genetic causes of my diabetes. This information may be shared with you and your clinician both now and in the future.
- allow the study team to have access to relevant sections of my medical notes that are relevant to my taking part in the study.

I understand that:

- individuals from regulatory authorities, or the Royal Devon & Exeter NHS Foundation Trust (the study sponsors) will have access to data collected during the study, and relevant sections of my medical notes, for monitoring and audit purposes.
- my participation is voluntary and that I may withdraw at any time without giving any reason and without my clinical care being affected.

OPTIONAL CONSENT STATEMENTS

- I am happy to complete the optional study questionnaires
- I agree that information held by the NHS and in my medical records may be used to follow up on my future health status.
- I agree to gift samples and data, collected during this study and as part of my routine diabetes care, to the Peninsula Research Bank and understand that they may be used in future research. I understand that these studies will be approved by a steering committee and my samples will not be used for any of the following: Sold for profit, used in animal research, used in research into the termination of pregnancy or reproductive cloning, screened for markers predictive of disease, with the exception of genetic causes of diabetes (see item 4 above). My samples may be provided anonymously to researchers from the UK and abroad including academic organisations and commercial companies.
- I am happy for my contact details to be used by the StartRight research team to inform me about future studies and I give consent for NHS-based staff to access my medical records to check my eligibility for future research

Before you make a decision about participating in this study extension, you may want to discuss the project with your GP or family members. The Patient Advice & Liaison Service at your local hospital can provide independent advice on participating in research.

Thank You For Taking Part In The StartRight Study