University of Exeter

NHS Royal Devon University Healthcare NHS Foundation Trust

BRIGHT

Benefits of Retained Insulin secretion for Good HealTh

A research project to understand

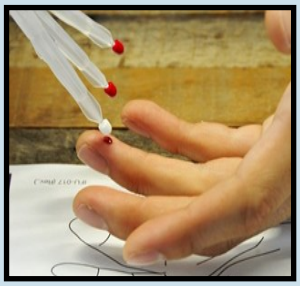
1. **The benefits of preserving insulin production for people living with type 1 diabetes.**
2. **The best way to measure insulin production.**

The Best Way To Measure Insulin Production

We are inviting you to take part because:

- You have had a test called C-peptide to measure your insulin production. The test may have been done in a research study or as part of your diabetes care.
- You have Type 1 diabetes





Taking part involves:

- A research clinic visit of about 2½ hours for a series of blood samples after drinking a liquid meal.
- A liquid meal at home & collection of some finger-prick blood samples.
- Wearing a continuous glucose monitor (CGM) on your arm for 14 days.

- Before you decide whether to take part, it is important to understand why the research is being done and what it will involve.
- Please take the time to read this study information carefully & discuss with family & friends if you wish.
- You are free to decide if you want to take part & deciding not to will have no impact on your NHS care.

This Research Is Funded By: Breakthrough T1D™ Formerly JDRF

1. Why are we doing this study?

We are doing this study to find out the best way to measure insulin production in people living with type 1 diabetes, and whether insulin secretion can be accurately measured at home, without a visit to hospital.

Many new treatments are being developed and tested for people living with type 1 diabetes to preserve their insulin secretion when diabetes is first diagnosed, or to restore insulin secretion by replacing the cells that make insulin. People taking part in these studies currently need many hospital visits to accurately test their insulin production using a test called a mixed meal test, where many blood samples are collected over 2 to 3 hours after a liquid meal. The samples are then tested for insulin levels, measured using C-peptide, which the body makes in the same amounts as insulin. The mixed meal test can be needed many times over months or years to accurately test changes in insulin production. This is difficult for participants, who will often need to miss work or school & travel long distances to a hospital. It also means that these studies can struggle to recruit participants, and are very expensive.

We believe these tests of insulin production can be undertaken at home and may be just as accurate. It is also possible that we can improve the test done in hospital to better test how well the cells that make insulin are working, therefore reducing how many people are needed for studies in this area.

To do this we will compare different ways of measuring insulin production, at home and in a research centre, and test how well these different ways of measuring insulin predict changes in glucose (such as variation in glucose and hypoglycaemia) using continuous glucose monitoring (CGM). Home tests will use fingerpick blood samples, collected in a shorter mixed meal test, together with a number of tests after a persons usual meals. The home testing methods have been used successful in other studies with very positive feedback from participants.

2. Why have you been invited to take part in this study ?

You are invited because you have Type 1 diabetes and have previously had a test called C-peptide to measure your level of insulin production. That test may have been in a research study (where you consented to be contacted for other studies) or done by your doctor. We are recruiting people with a range of their own insulin production as it is important we study people who make different levels of insulin. Taking part will involves one visit to the research centre followed by sample collections at home during a period of up to 4 weeks. Some people may be invited to do a second set of home sample collections up to 4 weeks after the first. **Please see the table in section 6 for more details about taking part.**

3. Who is organising this study ?

It is led by Professor Angus Jones, clinician scientist at the University of Exeter Medical School and diabetes consultant at the Royal Devon University Healthcare NHS Foundation Trust

It is Sponsored by the Royal Devon University Healthcare NHS Foundation Trust.
It is funded by Breakthrough T1D (formerly JDRF) https://www.breakthrought1d.org/about/
It is supported by the National Institute for Health & Care Research (NIHR) through the Exeter Biomedical Research Centre, Exeter Clinical Research Facility and Research Delivery Network at local sites.
It has been reviewed by:
The Peninsula Research Bank Patient & Public Involvement Groups
The Health Research Authority and independent National Research Ethics Committee (London—Stanmore REC) under IRAS reference number 347042

4. Who can you contact for more information ?

If you would like to discuss the study in more detail with the research team please contact:

Study Team Email: rduh.brightstudy@nhs.net
Telephone: 01392-408181
Chief Investigator Email: angus.jones@exeter.ac.uk

The study Sponsor is the Royal Devon University Healthcare NHS Foundation Trust. Email: rduh.research-eastern@nhs.net

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

Donation of blood samples can be uncomfortable but an experienced nurse / researcher will perform this procedure to minimise any discomfort and will monitor & support you. The project gives insights into glycaemic control but won't change your treatment. However, if we unexpectedly identify anything that could impact on your clinical care, we will inform your clinician/GP who may want to follow this up with you. Although the outcome of this research may not benefit you directly, it is important to the design of studies of new treatments to preserve insulin producing cells (beta cells) in the future and to C-peptide testing in clinical practice and other areas of research.

6. What will you need to do if you take part?

A) Before You Make A Decision About Taking Part:

- Please read this information leaflet and the consent form, and ask us any questions about taking part.
- Please feel free to discuss the study with family and friends before deciding.
- **You are free to choose whether to take part and deciding not to will have no impact on your standard NHS care.**

B) Mixed Meal Test (MMT) at Research Centre — approx. 2½ hours

- You will be asked to sign a consent form (copy provided with this leaflet) to confirm that you are happy to take part in the study.
- We will ask you to fast overnight (nothing to eat or drink, except water for at least 10 hours before your appointment time) and will advise you about your insulin dosing.
- We will ask you some questions about your diabetes and health, and take some measures (including weight, height & waist/hips).
- We will insert a small cannula (thin plastic tube) into your arm to make the collection of blood samples more comfortable.
- Samples will be collected from the canula at 6 specific times within 2 hours, before and after drinking a liquid meal replacement. The samples will be used to measure your body's own insulin production and other factors associated with T1D.
- We will ask you to complete questionnaires about your diabetes and your quality of life (online or paper format if preferred).
- We will fit a continuous glucose monitor (CGM) to your upper arm and talk through its use and how to remove it after 14 days.
- We will talk through the home test and finger prick sample collection and provide you with a remote study kit to take home.
- We will offer you a light lunch at the end of sample collection and reimburse travel expenses up to £10.

C) Mixed Meal Test (MMT) at Home — approx. 1½ hours & finger-prick sample collection on 3 days (approx. 15 minutes each).

(Ideally within 2 weeks of research centre visit but can be up to 4 weeks)

- Remote support provided by researcher (by telephone or video call)
- Overnight fast (as detailed in section b) above for MMT at research centre)
- Collection of finger-prick blood samples before drinking the liquid meal and at 90 minutes after.
- Collection of finger-prick blood samples, after a main meal, on 3 days following the MMT.
- Add date and time to all samples and post to the NHS clinical laboratory at the Royal Devon University Healthcare NHS Foundation Trust.
- Removal of the CGM (14 days after fitting) and post to study team.
- Option to provide feedback on your experience of taking part in the study.

D) Optional Repeat of Home MMT In Some Participants - approx.1½hrs

(Ideally within 2 weeks of first home MMT but can be up to 4 weeks)

- This additional procedure is optional and declining will not prevent you from taking part in the rest of the study.
- Collection of finger-prick blood samples before drinking a liquid meal and at 90 minutes after.

7. How will we use information about you?

In this research study we will need to use information from you, from your medical records, from your clinical care team. This information will include your NHS number, your name, your date of birth and your contact details. Your local research team and members of the study central coordinating team in Exeter will have access to that 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.

The Royal Devon University Healthcare NHS Foundation Trust is the study Sponsor and is responsible for looking after your information. We will keep all information about you safe and secure by ensuring that:

- Information is stored securely on password protected computers & paper documents in locked cabinets in offices with restricted access.
- People who need to access your information for this research have completed appropriate information security training.

For this research, patient identifiable data will not be shared outside the UK.

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

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 all of your full study data for a maximum of 5 years after the end of the study. The study data will then be fully anonymised (ie removing names, dates of birth & other data that could identify people in the study) and stored securely in an approved data store indefinitely (>30 years) for future use. That fully anonymised dataset may be shared with other researchers for the benefit of further research & healthcare improvement, eg sharing data with other diabetes researchers in future projects or to support NHS policy.

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.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this

If you agree to take part in this study, you will have the option to take part in future research using your data & any leftover samples saved from this study. If you agree, at the end of the study, we will transfer your data to the Peninsula Research Bank (PRB) for long term management, in order that you may continue to be contacted after this study is completed.

You can find out more about the PRB here: https://exetercrfnihr.org/about/exeter-10000-prb/

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

- Our leaflet available from www.hra.nhs.uk/patientdataandresearch
- By contacting us by email: rduh.brightstudy@nhs.net OR phoning us on 01392-408181
- By emailing the Sponsor's data protection officer: rduh.dpo@nhs.net

What will happen to the results of the study ?

The results will be published in appropriate medical and scientific journals and presented at conferences both in the UK and abroad. A summary of the study results will also be made available to all study participants.

8. Who to contact if you would like further advice or have a complaint

Please contact the study team or the Sponsor using the contact details in section 4 of this leaflet.

However, if you have concerns or complaints arising from your experience of participating in this study, which you do not wish to discuss with people directly involved in the research, the Patient Advice & Liaison Service, Tel: 01392 402093 or Email: rduh.pals-eastern@nhs.net can provide independent advice. 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 and seek any resulting compensation through the Royal Devon University Healthcare NHS Foundation Trust, the research sponsor. Also, as a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. To do so, you can submit a written complaint to the Complaints Team, Email: rduh.complaints-eastern@nhs.net. 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 against the **Royal Devon** but you may have to pay your legal costs.