Participant Information for Adults

At Risk of Autoimmune Diabetes

Invitation

- The ARAD study is following up previously identified adults and children who have one or more islet autoantibody markers which show that they are at risk of developing type 1 diabetes in the future.
- If you are eligible and decide to join the study, we will request a finger prick capillary blood sample and a mouth swab (DNA) sample which are both collected at home.
- From the capillary blood sample, we test to determine your current islet autoantibody status and we will inform you of this result. We will test the DNA sample for genes associated with type 1 diabetes to help with our research, these results are not reported.
- We will keep in touch with you each year for follow up and monitoring.
- You are free to decide whether to take part, this will not affect the care you receive from your own doctors.
- Please ask us if anything is not clear or you would like further information.

Thank you for considering taking part in this research project.

Scan QR Code to website

Introduction:

What is Type 1 Diabetes?

- T1D is an autoimmune condition. The immune system, which is meant to protect us from infections, such as viruses and bacteria, mistakenly attacks and destroys the beta cells in our pancreas that produce insulin.
- We all need insulin to live. It does an essential job. It allows the glucose in our blood to enter our cells and fuel our bodies.
- Tests developed in our laboratories can detect in a small blood sample whether proteins called islet autoantibodies are present. If so, this could mean that the insulin producing cells may be damaged.
- Islet autoantibodies can be found in the blood many years before type 1 diabetes occurs.

What is the purpose of the ARAD study?

- To follow up and monitor people who have previously been identified as being at increased risk of developing type 1 diabetes.
- To investigate what proportion of participants in ARAD develop type 1 diabetes, either rapidly or slowly and identifying the causes of this.

Who is eligible to take part?

- Previously identified adults and children who have one or more islet autoantibody markers which show that they are at risk of developing type 1 diabetes.

What will taking part involve?

If you decide to take part in the ARAD Study, we will ask you **on joining** to:

- Complete a form with your current contact details and your demographic details including your age, sex at birth, and relevant medical history.
- Complete a consent form.
- Volunteer a finger prick capillary blood sample.
- Volunteer a genetic DNA mouth swab sample.
- Complete a physical activity questionnaire.

Finger prick capillary blood test for Islet autoantibody measurement

- ❖ A few drops of blood are collected from a finger into a small tube. This sample is collected at home and returned via an ordinary post box in a prepaid packaging.
- ❖ How-to video guides and clear written instructions are provided.

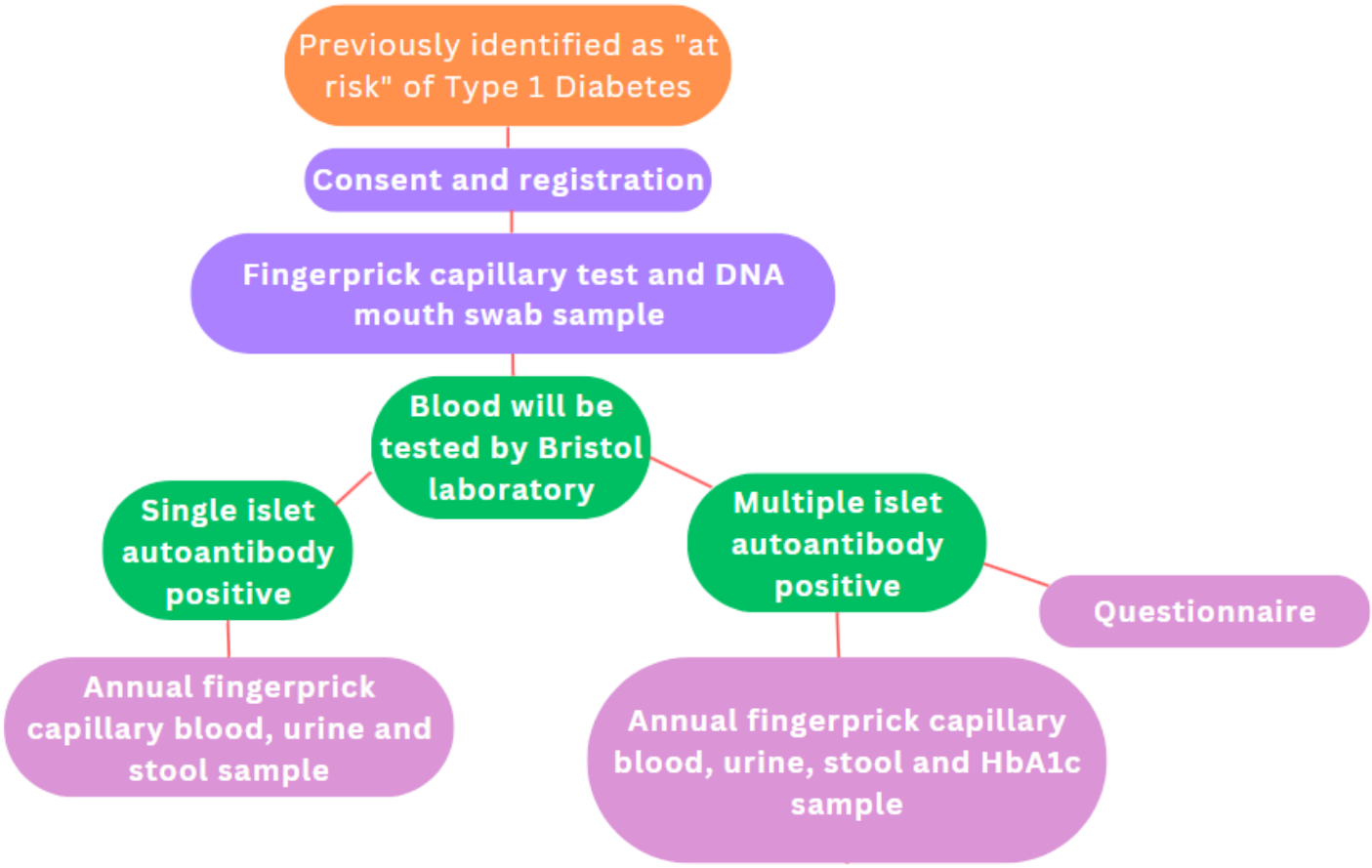
ARAD yearly follow up for one islet marker.

Participants who test positive for one islet marker will be invited to volunteer the following samples:

- Finger prick capillary blood is requested for the measurement of islet autoantibodies and enzymes in the pancreas.
- A urine sample is requested for measurement of Urinary C-peptide Creatinine Ratio (UCPCR) test. This test measures factors related to the function of the insulin producing cells.
- A stool sample. This allows us to test how the pancreas is functioning.

ARAD yearly follow up for two or more islet markers.

- Participants who test positive for **multiple** islet autoantibodies will be invited to volunteer follow up annual samples of finger prick capillary blood, urine, and stool.
- HbA1c blood sample: The HbA1c test measures average glucose levels 2-3 months before the test.
- Participants will be asked to complete a yearly update questionnaire.
- Participants will be informed of relevant clinical trials that may be of interest to them.
- Participants who test positive for **multiple** islet autoantibodies will be invited to take part in occasional mechanistic studies looking at Immune cell function. These studies involve volunteering larger volumes of blood.



Do I have to take part?

Taking part is completely voluntary, it is up to you whether you decide to take part. You can withdraw at any time, and you do not need to give a reason, the standard of your medical care or treatment you receive in the future will not be affected. If you choose to withdraw, any data already collected from capillary blood samples will be retained.

What are the possible benefits of taking part in ARAD?

It is clear from studies in children that when they and their parents know their risk of T1D, it helps prevent the child becoming seriously unwell with diabetic ketoacidosis (DKA) and therefore avoiding a late, emergency or life threating diagnosis. This may be similar in adults.

What are the possible disadvantages and risks of taking part?

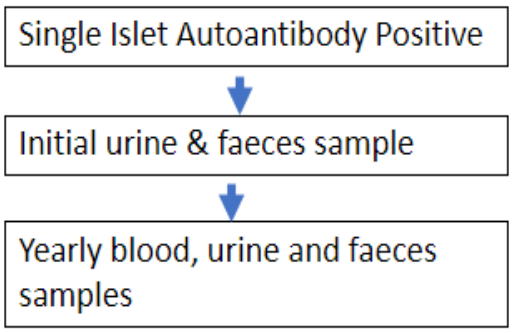
- You could have some soreness in your finger when using the lancet (finger prick device) to collect your capillary blood sample.
- Since this research involves studying islet autoantibodies that can predict getting type 1 diabetes, there are other kinds of risks. If our tests confirm that you continue to be at greater risk for T1D, this could make you worried. To reduce worry, at the time you are given any test results, we will explain their meaning to you and you can email us to request a call to discuss your results at any time.

Will I find out the results on any samples I give?

- **You will be given the results of your islet autoantibody tests.**

Islet autoantibody markers and annual sample follow up.

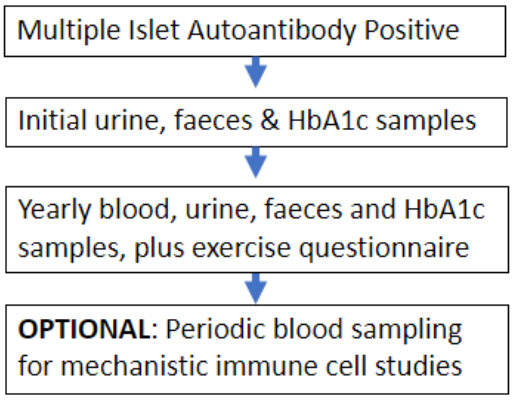
Routine laboratory testing usually takes eight to ten weeks to complete, you will then be informed of your result.



One islet autoantibody marker:

If we find **one** islet autoantibody, this is a positive result.

Research from previous studies in children shows that testing positive for one islet autoantibody **does not mean that you will go on to develop type 1 diabetes,** but you are at slightly increased risk when compared to someone who has tested negative. One of the aims of the ARAD study is to understand risk in adults who have one islet autoantibody.

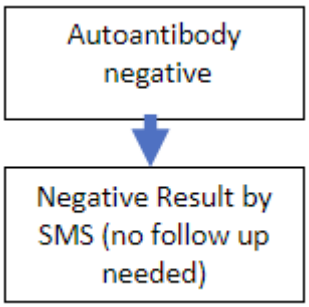


Two or more islet autoantibody markers:

If we find **two or more** islet autoantibody markers present, this is also a positive result.

Testing positive for two or more islet autoantibodies means that you may be more likely to develop T1D at some time in the future, when compared with other people who do not have these markers.

No islet autoantibody markers:



If we do not find islet autoantibodies, this is a negative result.

Testing negative for islet autoantibodies **does not mean you will never develop type 1 diabetes**, but the chances are much lower than a positive result.

HbA1c blood test

We will report this blood test result to you **if it is above the normal range**, which may indicate a change in your glucose control. You may wish to share this information with your GP.

How will my information be kept confidential?

- All information that is collected about you during the study will be kept strictly confidential.
- Any information that leaves the co-ordinating centre will have your name and address removed so that you cannot be recognised from it.

What will happen to any samples I give?

- Any samples we collect from you are stored using a unique code which can only be traced back to yourself via a secure database with restricted access.
- Samples will be used for research into type 1 diabetes and related autoimmune conditions e.g. Thyroid and Coeliac disease.
- Some samples we collect will be sent coded and anonymised to national and international research laboratories for further measurement. Any results and correspondence will be made using this code and strict data protection guidelines will be adhered to.
- Samples will be kept long term to allow us to go back to them in the future should new techniques/research questions be developed.
- If you decide to withdraw in the future, any data and samples you have given will be anonymised but remain associated with the project.

General Data Protection Regulation (GDPR) Information:

The University of Bristol is the sponsor for this study based in Bristol, United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Bristol will keep identifiable information about you for 15 years after the study has finished.
Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

The only people in the University of Bristol who will have access to information that identifies you will be people who need to contact you to provide study updates or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

Further information about how the University of Bristol uses research participants' personal data can be found here:

https://www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/

What will happen to the results of the research study?

Results from the research are published regularly in peer reviewed scientific journals and these are made available on our website. Any reports or presentations about the study will be written in a way that no-one can identify anyone who took part.

What if there is a problem?

It is highly unlikely that anything will go wrong. If taking part in this research project harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay your legal costs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during this study please contact us using the details given at the end of this information sheet.

Who is organising and funding ARAD?

The study is supported by individual project-based grants from charities including the Leona M. and Harry B. Helmsley Charitable Trust, Diabetes UK and JDRF. There are no commercial interests involved in the study.

Who has reviewed the study?

ARAD has been reviewed and approved by NHS Health Research Authority (reference number 23/NW/0305).

Who should I talk to if I have any questions or concerns?

You are encouraged to ask all questions which come to your mind about the study. You can contact us using the details below.

Thank you once again for reading this information and taking the time to consider taking part.

Contact us:

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