Participant Information

Type 1 diabetes (T1D) risk in adults

- T1DRA is the first **general population study in the UK** aiming to identify **adults aged 18-70** for their future risk of developing type 1 diabetes.
- Everyone taking part is helping us to understand more about the pathways that lead to a diagnosis of type 1 diabetes in adults.
- Using a **finger prick blood test collected at home**, we will tell you if you have markers of increased risk of type 1 diabetes by testing for the presence of proteins called islet autoantibodies.
- We encourage people from all backgrounds and ethnicities to take part in T1DRA so our findings can accurately represent the adult UK population.
- Taking part is completely voluntary.
- Please ask us if anything is not clear or you would like further information.

Thank you for considering taking part in this research project.

What is Type 1 Diabetes?

- Type 1 diabetes 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 T1DRA study?

- Previous studies have shown that 3 in 1000 **children** (0.3%) have two or more islet autoantibodies in their blood. Over 80% of these develop type 1 diabetes by the age of 20 years.
- Our main aim is to find out how many **adults** in the UK general population are at risk of developing type 1 diabetes before they become unwell.
- Those people found to be at increased risk will be supported and provided with the best current advice on risk, monitored with follow up samples and given further information on follow up studies.

Who is eligible to take part?

- People living in the UK aged between 18 and 70 years that do **NOT** have a diagnosis of type 1 diabetes.
- People who are **not** taking blood thinning medication or immunocompromised.

What will taking part involve?

- Once you have read this information, if you would like to take part in the T1DRA Study, you can enrol on our website and complete some consent questions to ensure your understanding of the study.

- We require your contact details and information such as your age, sex at birth, ethnicity, any relevant medical conditions. We will also ask about any family history of type 1 diabetes.

The finger prick capillary blood test

On receipt of your consent, we will send you a finger prick kit in the post to your home address with full instructions and return freepost packaging.

A few drops of blood are collected from a finger into a small tube, with or without a feeder straw.

- This sample is collected at home and returned via an ordinary post box.
- How to video-guides and clear written instructions are provided.

How will I find out the results on any samples I give?

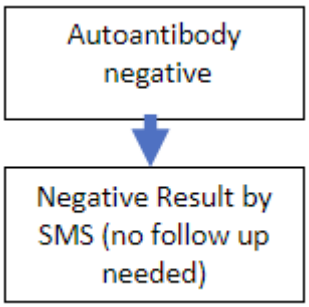
Islet autoantibody markers

- Routine laboratory testing usually takes eight to ten weeks to complete subject to demand.
- People that have no islet autoantibody markers (test negative) will receive their result by text message (SMS).
- People that have one or more islet autoantibodies (test positive) will be asked to volunteer a repeat finger prick sample to confirm the result. This is common procedure in our research as islet autoantibody levels can fluctuate, especially if the levels are low.

- People that are confirmed positive for one or more islet autoantibodies will be contacted by our study nurse and receive their result by email/letter.

Islet autoantibody markers and T1DRA yearly follow up.

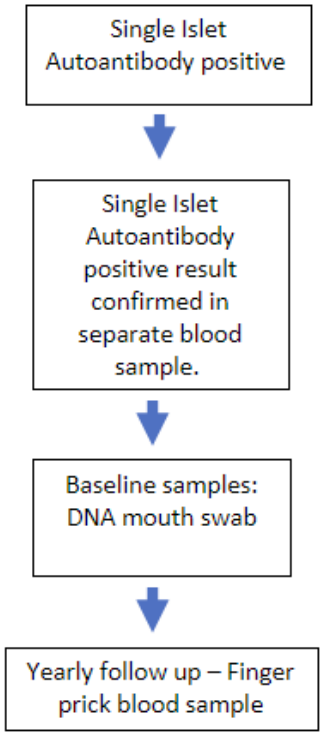
No islet autoantibody markers*:*



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.

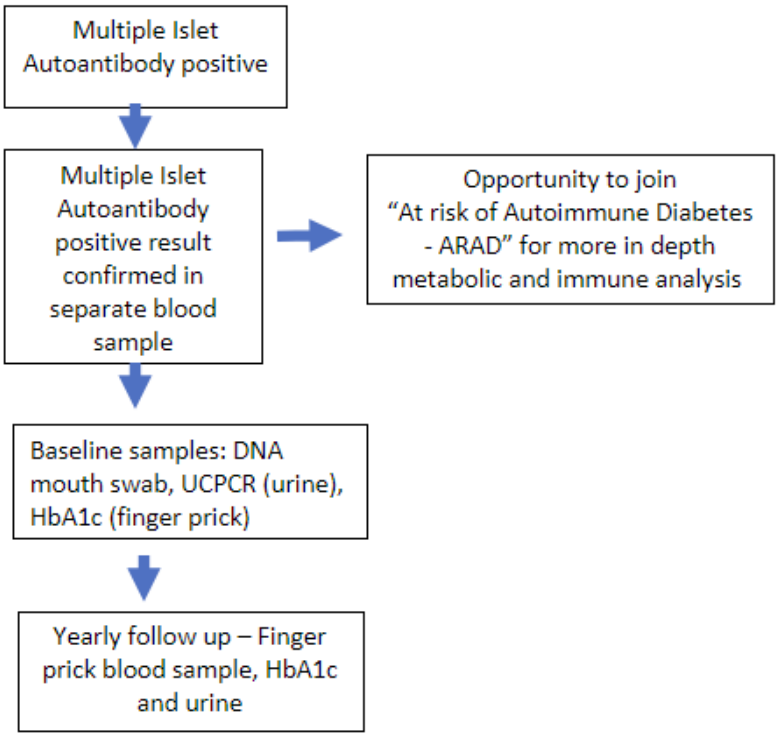
One islet autoantibody marker:



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

Previous studies in children show that the presence of one islet autoantibody slightly increases the risk of developing type 1 diabetes when compared to other people that do not have these markers. One of the aims of the T1DRA 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 type 1 diabetes at some time in the future, when compared with other people who do not have these markers.

What are the possible benefits of taking part?

It is clear from studies in children that (by their parents) knowing about risk of type 1 diabetes helps prevent becoming seriously unwell with very high levels of blood sugar. This condition is called diabetic ketoacidosis (DKA) and can be an emergency or life-threatening medical condition.

T1DRA testing aims to help prevent DKA in adults by informing them of their future risk of developing type 1 diabetes.

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 developing type 1 diabetes, there are some associated risks. If you learn that you are at greater risk for type 1 diabetes, this could make you feel anxious. To

reduce worry, at the time you are given any test results, we will explain their meaning to you and offer annual follow-up as a form of ongoing support.

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.
- 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.

What if I change my mind?

You can withdraw at any time, and you do not need to give a reason. If you withdraw, any data already collected from samples will be retained.

How will my information be kept confidential?

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

General Data Protection Regulation (GDPR)

The University of Bristol is the sponsor for this study based in Bristol, United Kingdom. We will be using information from you 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 T1DRA research will be published on our website and in peer reviewed scientific journals. 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 T1DRA?

T1DRA is supported by the Helmsley Charitable Trust but other organisations have funded various aspects of the work. There are no commercial interests involved in the study.

Who has reviewed the study?

T1DRA has been reviewed and approved by the 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.

CONTACT US:

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