

# Characterising new-onset type 1 diabetes and supporting type 1 diabetes research

|                                        |                                                                |                                                                                                   |
|----------------------------------------|----------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>16/10/2017   | <b>Recruitment status</b><br>Recruiting                        | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>08/03/2018 | <b>Overall study status</b><br>Ongoing                         | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>26/05/2026       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

### Background and study aims

Diabetes is a life-long condition that causes a person's blood sugar to become uncontrolled and too high. This condition usually forms while someone is young. There are similarities in the presentation of type 1 diabetes, for example, similarities in some symptoms, but there are also many differences. An up-to-date picture of type 1 diabetes at onset in children and adults in modern and diverse Britain is needed to improve understanding of these similarities and differences. There are other studies that are investigating ways of preserving beta cell function soon after diagnosis, but finding people to take part in these studies can be challenging. The aim of this study is to help to put people interested in taking part in research in touch with researchers running studies. It also supports other research by making the anonymous information blood and DNA samples collected in the study, available to other researchers.

### Who can participate?

Children aged from 1 year and adults of any age who have had type 1 diabetes for less than 6 months. Siblings without diabetes can also participate.

### What does the study involve?

Participants have an interview with a researcher to collect information about medication, medical history and family history and onset of diabetes (not siblings). An optional blood sample for testing and storage of blood and DNA is taken from participants. Participants allow the study team to collect health information from medical records and from central NHS systems. Participants are asked to consent to being contacted about other diabetes research, but are under no obligation to take part in other research. They are also asked to consent to the sharing of their anonymous information and biological samples for other research relevant to diabetes.

### What are the possible benefits and risks of participating?

There is no direct benefit to participants. An improved understanding of type 1 diabetes at onset may lead to benefits for people with type 1 diabetes in the future. Giving a blood sample has a risk of bruising and discomfort.

Where is the study run from?

This study is being run by Imperial College London (UK) and takes place in hospitals across the UK.

When is the study starting and how long is it expected to run for?

July 2010 to December 2026

Who is funding the study?

Diabetes UK (UK)

(Note: Juvenile Diabetes Research Foundation Limited (JDRF) (UK) funded between July 2010 to December 2018)

Who is the main contact?

Dr Akaal Kaur, address2@imperial.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

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# Additional identifiers

## Integrated Research Application System (IRAS)

55225

## Protocol serial number

CPMS 9689

# Study information

## Scientific Title

An incident and high risk type 1 diabetes research cohort - After Diagnosis Diabetes REsearch Support System-2 (ADDRESS-2)

## Acronym

ADDRESS-2

## Study objectives

The aim of this study is to characterise new-onset type 1 diabetes in the modern and diverse UK population. To link people wanting to participate in type 1 diabetes research with researchers and studies. To support other type 1 diabetes research via an open access repository of data and biological samples.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 03/10/2010, South Central – Berkshire NHS Research Ethics Committee (Bristol HRA Centre, Bristol, BS1 2NT, United Kingdom; +44 (0)207 104 8178; berkshire.rec@hra.nhs.uk), ref: 10/H0505/85

## Primary study design

Observational

## Study design

Observational; Design type: Cohort study

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Type 1 diabetes mellitus

## Interventions

Demographic, clinical and routine laboratory data are collected via interview with participants and from their medical records at a single study visit. An optional blood sample is collected for the measurement of islet autoantibodies (markers of autoimmune activity in type 1 diabetes), extraction and storage of DNA and storage of blood. Within the first year of diagnosis, follow-up data are collected from medical records to confirm or record a change in diabetes sub-type.

**Intervention Type**

Other

**Primary outcome(s)**

Autoantibody status is measured in a single laboratory using established radiobinding assays at baseline and characteristics at presentation are measured using patient interviews, medical records and pathology systems at baseline.

**Key secondary outcome(s)**

There are no secondary outcome measures.

**Completion date**

31/12/2026

**Eligibility****Key inclusion criteria**

Current inclusion criteria as of 29/08/2024:

1. Age  $\geq 1$  years
2. Male or female
3. Clinical diagnosis of type 1 diabetes or unclassified but possible type 1 diabetes and have been diagnosed less than 6 months at the time of recruitment or the sibling of someone meeting the criteria above who has consented to the study. Sibling must be free from diabetes

Previous inclusion criteria:

1. Age  $\geq 5$  years
2. Male or female
3. Clinical diagnosis of type 1 diabetes or unclassified but possible type 1 diabetes and have been diagnosed less than 6 months at the time of recruitment or the sibling of someone meeting the criteria above who has consented to the study. Sibling must be free from diabetes

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

1 Years

**Upper age limit**

100 Years

**Sex**

All

**Total final enrolment**

## **Key exclusion criteria**

Current exclusion criteria as of 29/08/2024:

1. Children under 1 years of age
2. Individuals aged 16 years or older who are not competent to give consent
3. Recently diagnosed type 1 diabetes participants, who have been previously diagnosed with type 2 diabetes, unless the initial diagnosis of type 2 diabetes is also within 6 months prior to enrolment

Previous exclusion criteria:

1. Children under 5 years of age.
2. Individuals aged 16 years or older who are not competent to give consent.
3. Recently diagnosed type 1 diabetes participants, who have been previously diagnosed with type 2 diabetes, unless the initial diagnosis of type 2 diabetes is also within 6 months prior to enrolment

## **Date of first enrolment**

01/07/2011

## **Date of final enrolment**

31/12/2026

# **Locations**

## **Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

## **Study participating centre**

**Charing Cross Hospital (Lead Centre)**

Fulham Palace Road

London

England

W6 8RF

# **Sponsor information**

## **Organisation**

Imperial College of Science, Technology and Medicine

**ROR**

<https://ror.org/041kmwe10>

## Funder(s)

**Funder type**

Government

**Funder Name**

Diabetes UK

**Alternative Name(s)**

The British Diabetic Association, DIABETES UK LIMITED, British Diabetic Association

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

**Funder Name**

Juvenile Diabetes Research Foundation

**Alternative Name(s)**

Juvenile Diabetes Research Foundation Ltd, JUVENILE DIABETES RESEARCH FOUNDATION LIMITED, JDRF UK, JDRF

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during the current study and stored DNA and blood samples are available upon application to the ADDRESS-2 Management Committee. The datasets include demographic, clinical and laboratory data. The access procedures and application forms are available on the study website (<https://www.address2.org>). Enquiries should be addressed to Ms Akaal Kaur ([address2@imperial.ac.uk](mailto:address2@imperial.ac.uk)). Consent was obtained from participants for their anonymous data and biological samples to be shared for diabetes research. The research must have independent ethical approval and the approval of the ADDRESS-2 Management Committee.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------------------------------------|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               | results                       | 04/04/2018   |            | Yes            | No              |
| <a href="#">Protocol article</a>              | protocol                      | 12/07/2017   |            | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |
| <a href="#">Study website</a>                 | Study website                 | 11/11/2025   | 11/11/2025 | No             | Yes             |