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

Submission date
16/10/2017

Recruitment status
Recruiting

Registration date
08/03/2018

Overall study status
Ongoing

Last Edited
16/04/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 5 years 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 April 2025

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?
Ms Akaal Kaur
address-2@imperial.ac.uk

Study website
http://www.address2.org/

Contact information

Type(s)
Scientific

Contact name
Ms Akaal Kaur

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-
-
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Additional identifiers

EudraCT/CTIS number

IRAS number
55225

ClinicalTrials.gov number

Secondary identifying numbers
CPMS 9689, IRAS 55225

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

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
The patient information sheets are available on the study website https://www.address2.org

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 measure
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.

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
01/07/2010

Completion date
31/03/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 29/08/2024:
1. Age ≥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 ≥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

Age group
Mixed

Lower age limit
1 Years

Sex
Both

Target number of participants
Planned Sample Size: 10,000; UK Sample Size: 10,000

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
31/03/2026

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Charing Cross Hospital (Lead Centre)
Fulham Palace Road
London
United Kingdom
W6 8RF

Sponsor information

Organisation
Imperial College of Science, Technology and Medicine

Sponsor details

-
-
United Kingdom
-

Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Diabetes UK

Alternative Name(s)
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

Publication and dissemination plan

Current publication and dissemination plan as of 25/03/2020:
The protocol has been published: https://www.ncbi.nlm.nih.gov/pubmed/28706084. Preliminary results have been published: https://www.ncbi.nlm.nih.gov/pubmed/29622578. Planned publications of sub-analyses in 2020 and beyond.

Previous publication and dissemination plan:
The protocol has been published: https://www.ncbi.nlm.nih.gov/pubmed/28706084. Planned publication in a high-impact peer-reviewed journal. Intention to publish preliminary results early in 2018, followed by subsequent publications in 2019 and beyond.

Intention to publish date

31/07/2024

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). 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?
Protocol article	protocol	12/07/2017		Yes	No
Results article	results	04/04/2018		Yes	No