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ELSA - Screening for type 1 diabetes in children

Submission date
15/04/2024

Recruitment status
Recruiting

Registration date
17/06/2024

Overall study status
Ongoing

Last Edited
12/08/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 1 diabetes (T1D) is the most common form of childhood diabetes. Here, cells that make insulin don't work as they should. Therefore, to stay alive and avoid the complications of diabetes, children have to monitor their glucose levels and inject insulin to keep the glucose levels within range for the rest of their lives.
Studies have recently shown that some medicines can safely delay children from getting T1D. Many children and parents tell us that these studies are very exciting because it could mean the end to T1D in children.
Other countries are developing surveillance systems to accurately tell which children are at risk of T1D. These children can then be offered participation in prevention studies. Such a system will also prevent children being diagnosed as an emergency. The UK does not have such a system. However, when we discuss setting up a T1D surveillance system with UK parents, they have different views on whether/how they would take part. No one has previously explored these questions in detail with parents and children and they tell us it is important to do so. We also do not know the best way to recruit large numbers of children into a surveillance programme.
The aim of this study is to develop a system for identifying children within the UK general population who are at risk of developing T1D. Such a system will allow children to take part in clinical trials for the prevention of T1D and help to reduce late diagnosis of T1D and the associated deaths in children. This study will explore three crucial questions:
1. What is the best way to recruit children to an early detection programme?
2. What are the views of parents and children about taking part in an early detection programme?
3. What are the views of doctors, nurses and school staff who will be involved in running an early detection programme?

Who can participate?
Any child between the ages of 3 and 13 years who does not already have T1D

What does the study involve?
Over 7 years, this study will test different approaches to recruiting a total of 50,000 children aged 3-13 years to take part in a surveillance programme. These approaches will include:
1. GP practices
2. Online
3. Vaccination programmes

4. Schools
5. National T1D networks

The researchers will ensure different ethnicities and levels of deprivation are represented and explore which recruitment approach(es) works best across all these populations.

Those who agree to participate will be asked to take a finger-prick blood sample from their child to analyse for T1D risk. This simple blood test can tell if a child will develop T1D over the next 15 years. The child will be managed according to the result. This may involve reassurance if the test is negative, and enrolment into a prevention trial or referral to a doctor for insulin treatment if the test is positive.

All parents, regardless of their child's participation in the blood test, will be interviewed about their views on testing for T1D risk to help us to understand how best to design a surveillance programme and how best to address any barriers to participation. The researchers will also interview doctors, nurses and school staff who may be involved in this study.

What are the benefits and risks of participating?

The immediate benefit is reducing the number of children being diagnosed as a diabetic emergency (DKA). Currently 750 children with T1D in the UK are diagnosed as a DKA and up to three of them will unfortunately not survive. Surveillance programmes reduce this fivefold, and this benefit will be there as soon as the programme starts.

The longer-term benefit will be offering prevention studies to those children found to be at risk of T1D. Some medicines have been shown to safely delay children getting T1D by over 3 years. In the UK, this therapy would delay T1D in 1800 children every year. Parents and children with T1D are very clear that "even one day without insulin injection would be great". With an estimated cost of £3000 per year for each child with T1D, a 3-year delay equates to an estimated £5.5 million pounds saving a year just for treatment costs. Other medicines are becoming available which need to be tested. We will be able to offer these medicines to explore which is the most effective and whether they can be used together to delay T1D for even longer.

This study has the potential to completely change how we manage T1D in the UK. It is hoped that it will help bring about the beginning of the end of this condition.

It will be the first study to tell us the views of children and parents about taking part in a study of T1D risk, how best to address any problems, and what is the best way to recruit children into the programme. It will also tell us the views of professionals who will be involved in running the programme.

The researchers will use the results of this study to design the most patient-friendly and easy-to-implement programme for children at risk of T1D.

The design of the final implementation programme will depend on the results of this study, but it will likely require the researchers to work with public health. For example, if GP surgeries are found to be a good way to recruit to studies, they will work with Public Health England to explore how GP surgeries can support the national roll-out of the study. With this end in mind, the researchers have already asked people with expertise in public health to be involved in this study.

There are also risks with the study. Firstly, there is the pain associated with a fingerprick blood test and possibly other blood tests if the first fingerprint blood test is positive. These blood tests are minor and at worst may be associated with untoward effects such as fainting or bruising at the site of the blood taking. There is also the risk of anxiety that may come with a positive screening result. If families find this particularly upsetting, the researchers have a number of ways to support them. First, they can offer an intensive education program so families are fully aware of what the future may hold and they are prepared for it. If necessary, they can also refer them to a clinical psychologist who can help talk through the problem and use their experience and techniques to help the families manage their anxiety.

Where is the study run from?
University of Birmingham (UK)

When is the start date?
November 2019 to August 2029

Who is funding the study?
1. Diabetes UK
2. Juvenile Diabetes Research Foundation (UK)

Who is the main contact?
elsa@contacts.bham.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
309252

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 52726

Study information

Scientific Title
Early Surveillance for Autoimmune diabetes: the ELSA study

Acronym
ELSA

Study objectives
Research aims
The overarching aim is to develop a system for identifying children in the general population who are at risk of type 1 diabetes (T1D). This will:
1. Increase participation in clinical trials to accelerate strategies to delay onset and prevent this condition.
2. Reduce late presentation of T1D, associated mortality and long-term complications.
3. Consequently, pave the way for a national early surveillance programme for T1D in the general population.

Research Objectives
1. Understand the perceptions and acceptability of families in the UK to be involved in a surveillance programme for early T1D, to establish how they would want to be informed and participate, and how any barriers to recruitment and participation can be addressed.
2. Determine the best approach to recruitment into a surveillance programme for T1D risk through examining the feasibility of a variety of approaches.
3. Understand the views of health care professionals, school staff and other stakeholders involved in the testing programme.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/06/2022, Wales Research Ethics Committee 4 Wrexham (Health and Care Research wales, Castlebridge 4, 15-19 Cowbridge Road, East Cardiff, CF11 9AB, United Kingdom; +44 (0) 2920 785738; Wales.REC4.@wales.nhs.uk), ref: 22/WA/0119

Study design
Observational cross-sectional study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Type 1 diabetes

Interventions
The ELSA study is a screening programme to find out children’s risk of developing T1D. Families will be recruited from the community, including general practices, schools, and vaccination

programmes. The first screening test is a finger stick dried blood spot (DBS), which can be performed at home, at GP practices or in the community and will test for islet antibodies including IAA, IA2, GAD, and ZnT8.

Children who are positive for any of the antibodies will attend for a confirmatory venous blood test (gold standard) at a regional clinical research facility (CRF). Parents of children who are DBS negative will be informed by text message and email/letter, and no further follow-up is required.

Children who are single or double antibody positive or venous confirmation negative will be informed by a phone call from a clinical member of the ELSA study team followed by an email /letter. Children who are multiple antibody positive will be invited to attend for an oral glucose tolerance test to further stratify their stage of T1D risk.

All children who are single or multiple antibody positive will be invited to attend an education session to provide information on their risk of future T1D and about research studies they may be eligible for, including trials, monitoring programmes, and natural history studies. Children at stage 3 will be referred into clinical service to commence insulin therapy. They will also receive information about any research studies they may be eligible for.

Families who have participated in the ELSA study or who expressed interest will be invited to take part in qualitative interviews to understand acceptability for screening. Stakeholders who were involved in the delivery of the ELSA study, including recruitment, consenting, and sampling of children enrolled in ELSA will also be invited to take part in a qualitative interview to obtain feedback on the screening process. This will be a purposive sample. Families who decided not to proceed with the ELSA study but were eligible and expressed interest, will also be invited to a qualitative interview to understand their reasons for not proceeding.

Intervention Type
Other

Primary outcome(s)
1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study by 24 months through online, primary care, school-based and other routes of recruitment
2. Acceptability of screening for diabetes as assessed by qualitative interviews with families and stakeholders at a single timepoint

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/08/2029

Eligibility

Key inclusion criteria
1. Children aged 3-13 years inclusive
2. Children of parents/guardians who consent to participation

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
13 years

Sex
All

Key exclusion criteria
1. Children with a previous diagnosis of T1D
2. Children of parents/guardians who are unable/unwilling to consent to participation
3. Currently enrolled in any other screening programme for T1D
4. Where in the view of the PI, participation is not in the best interests of the child

Date of first enrolment
01/11/2022

Date of final enrolment
30/08/2029

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Birmingham Children's Hospital
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Alder Hey Children's NHS Foundation Trust ,
NIHR Alder Hey Clinical Research Facility
1st floor Alder Hey Children's NHS Foundation Trust
East Prescot Road
Liverpool
United Kingdom
L14 5AB

Study participating centre
Royal Devon and Exeter Hospital
Research and Development Child Health Building Room F6
Barrack Road
Exeter
United Kingdom
XX2 5DW

Study participating centre
Children and Young Adults Research Unit
Noah's Ark Children Hospital for Wales
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Leeds Teaching Hospitals NHS Trust
Paediatric Diabetes Team 1st Floor,
Multispecialty Unit
St James University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Freeman Hospital
Newcastle upon Tyne Hospital NHS Foundation Trust
Freeman Road
High Heaton
Newcastle
United Kingdom
NE7 7DN

Study participating centre
Southern Health and Social Care Trust
Paediatric Outpatients
Daisy Hill Hospital Road
Newry County Armagh
Craigavon
United Kingdom
BT35 8DR

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
East Lancashire Hospitals NHS Trust
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
The Royal London Hospital
Barts Health NHS Trust
Whitechapel
London
United Kingdom
E1 1FR

Study participating centre
Royal Aberdeen Children's Hospital
NHS Grampian
Paediatrics Beech House
Aberdeen
United Kingdom
AB25 2ZG

Study participating centre
Tayside Children's Hospital
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

Study participating centre
Glasgow Children & Young People's Diabetes Diabetes Service
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow
United Kingdom
G3 8SI

Study participating centre
University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

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 United Kingdom

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 following identifiable data will be collected from parents or legal guardians:
1. Title and name (first and last name of parent/guardian)
2. Age (years) – to ensure representation across age groups in the study
3. Ethnicity – to ensure representation across ethnic groups in the study
4. Gender – to ensure representation across genders in the study
5. Address (postcode) – for communication purposes with the study team and to post out study documents
6. Postcode for deprivation level and eligibility
7. Email – for communication purposes with the study team
8. Phone number – for communication purposes with the study team
9. Parent/guardian status – to ensure representation across types of parent/guardian
10. Occupation – to ensure representation across socioeconomic groups

The following identifiable data of children will be collected from consenting parents or legal guardians:
1. Name (first and last name) – for the consent form
2. Age (years) – to check for eligibility for the study
3. Ethnicity – to ensure representation across ethnic groups in our study
4. Gender – to ensure representation across genders in our study
5. Medical history, including coeliac disease and thyroid disease
6. Family history of T1D (FDR)
7. GP details, including address, email and phone number

The following identifiable data will be collected from stakeholders:
1. Title and name (first and last name of parent/guardian)
2. Age (years) – to ensure representation across age groups in the study
3. Ethnicity – to ensure representation across ethnic groups in the study
4. Gender – to ensure representation across genders in the study
5. Address (postcode) – for communication purposes with the study team and to post out study documents
6. Email – for communication purposes with the study team
7. Phone number – for communication purposes with the study team
8. Occupation – to ensure representation across socioeconomic groups

The process for requesting access: Contract basis only with all enquiries to the study sponsor: elsa@contacts.bham.ac.uk

Consent was required from parents, and assent from children aged 5 years and above.

All essential documentation and study records will be stored by the Study Team in conformance with the applicable regulatory requirements and access to stored information will be restricted to authorised personnel including sponsor representatives and regulatory authorities.

All clinical, demographic data and personal details will be stored in separate forms in REDCap. The REDCap eligibility form, consent form, assent form and personal details form will predominantly be completed online by the parent/guardian. Alternatively, the participant can arrange a phone call or video consult with the study team, who will transcribe the information into the REDCap forms on behalf and with the consent of the parent/guardian.

All participant data will be pseudo-anonymised in REDCap using a unique study identifier.

All sample study numbers and results will be recorded on the electronic laboratory system Telepath to enable an audit trail which is a UKAS-accredited NHS IT system. Telepath sits within the University Hospitals Birmingham (UHB) NHS secure server despite the laboratory being sited in the University of Birmingham. Only the CIS members of the research team have login access to Telepath for personal details and coding. UHB will be the custodian of this personal data. Pseudo-anonymisation will take place in Telepath using the unique study identifier, year of birth and initials of the child.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes