UNIVERSITY OF BIRMINGHAM

ELSA

The ELSA study: EarLy Surveillance for Auto-immune diabetes

Parent's and Carer's information leaflet

Invitation:

As a parent or carer, of a child aged 3-13 years, your child is invited to take part in a screening programme for type 1 diabetes.

This leaflet will give you more information about the ELSA study. You can also visit our study website for an online version of this information sheet: www.elsadiabetes.nhs.uk.

Part 1 - ELSA Summary:

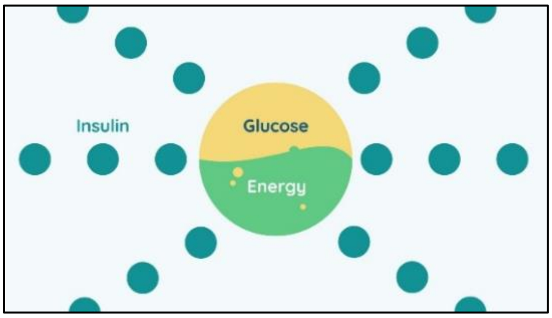
The ELSA study is testing children using a finger stick blood test, to find markers in the blood (autoantibodies), that tell us your child's risk of getting type 1 diabetes in the future.

3 out of 1000 children will test positive for these antibodies, but we have no way of knowing which 3 children this will be.

ELSA is the largest antibody screening programme for type 1 diabetes in the UK. Every family that takes part in our study is helping us to understand more about type 1 diabetes for children at risk.

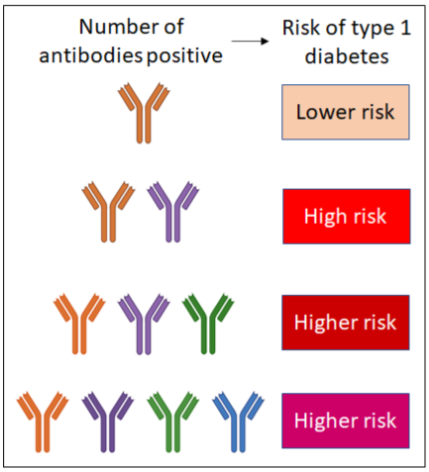
Part 2 – More about the ELSA study:

What is type 1 diabetes?



- Type 1 diabetes is a serious condition where the blood glucose (sugar) level is too high because the body cannot make a hormone called insulin.
- This happens when the body's immune system attacks the cells in the pancreas that make the insulin, meaning no insulin can be made.
- Antibodies contribute to this process.
- 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.

Around the world, research studies are screening children for type 1 diabetes, so that we can find children at risk before they become unwell.



What does the ELSA study involve for your child?

The ELSA study is testing children for antibodies, to find those at high risk of developing type 1 diabetes in the future. The ELSA study is testing for 4 different antibodies called IAA, IA2, ZnT8 and GAD. As the number of antibodies a child has rises, this increases their risk of developing type 1 diabetes in the future.

The ELSA study wants to find children with antibodies so that we can help sooner by:

- Stopping high risk children from becoming too unwell, by starting treatment sooner.
- Offer further research studies that monitor children's risk over time.
- Trial new treatments which aim to delay the start of type 1 diabetes.

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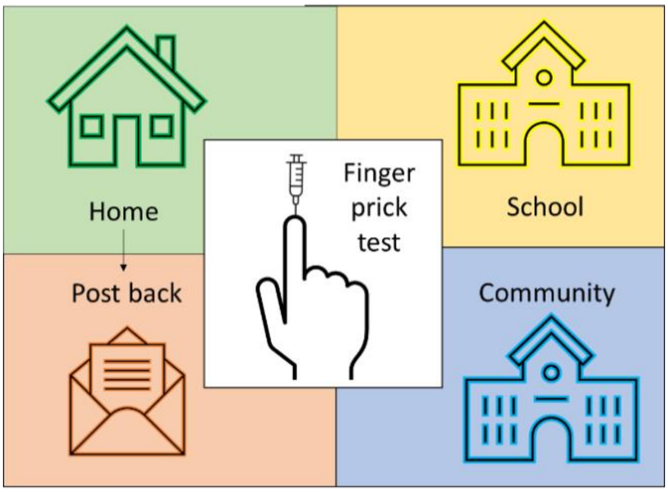
What will happen if I agree for my child to take part in the screening programme?

If you decide to enrol your child in the ELSA study, we will first check your child is eligible for the study and then you will need to complete a consent form for your child to take part. After this, you will need to fill out some study forms to provide your contact details and your child's demographic details, including your child's age, sex at birth, ethnicity and relevant medical history.

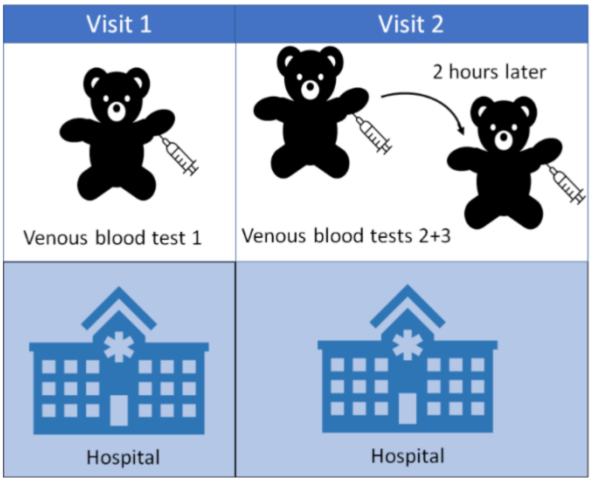
Step 1 – Finger stick blood test:

- The finger stick blood test can be done from home, at school, or at the GP surgery. This is the first screen to see if your child has type 1 diabetes antibodies.
- **Antibody negative test:** If your child tests negative, this means your child does not have antibodies and are currently at low risk of developing type 1 diabetes. Your child will not need any further tests in the ELSA study (99 in 100 children will screen negative).
- **Antibody positive test:** If your child tests positive, this means your child has antibodies on this first screen and will need a venous blood test at the hospital to confirm this. We can cover your travel costs, if you are able to provide evidence of your travel, such as receipts.



Step 2 – Venous blood test:

- 1 in 100 children in our study will need the venous blood test. We will take up to 1 tablespoon of blood (up 15ml) depending on the age of your child.
- **Antibody negative test:** If your child tests negative on the venous blood test, we will not need to do any more tests in the ELSA screening programme (step 4-6).
- **1 Antibody positive test:** If your child tests positive for 1 antibody, this means your child is at some risk of developing type 1 diabetes in the future. You and your family will be invited to an education session to explain what this means (step 4-6).
- **2 or more Antibody Positive test:** If your child tests positive for 2 or more of the antibodies, this means your child will almost certainly develop type 1 diabetes. Your child will therefore need some more blood tests (step 3-6).



Step 3 – Oral glucose tolerance test (more venous blood tests)

- If your child has **2 or more antibodies**, your child will need to have some more blood tests to see if insulin needs to be started straight away. The amount of blood will depend on the age of the child but may be 2-4 tablespoons or 30-60ml.
- Your child will need to fast overnight, and then will be cannulated so that blood can be taken at six time points over 3 hours. Your child will also be given a glucose drink for this test.
- This test will be done at the hospital and we can cover your travel expenses and can offer accommodation for you and your child. The study team will refer your child into the children's diabetes service if clinically necessary and will call you to discuss this.

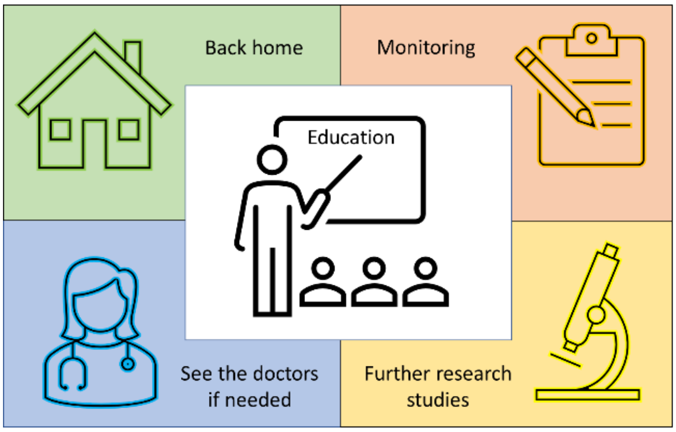
Step 4 – Screening results and Study questionnaire

- The study team will inform you of your child's screening test results. If your child is negative, you will receive a text message and an email/letter, depending on your contact preferences. You will also receive some information about what this negative result means.
- If your child is positive, the study team will call you and send an email/letter to explain what the next steps are.
- With your consent, we will inform your child's GP of the antibody result by letter, so that your child's risk status can be included in NHS clinical systems to help in the future.
- Once you have received your child's result, we will ask you to fill in a study questionnaire to understand any worries you may have.

Step 5– Education

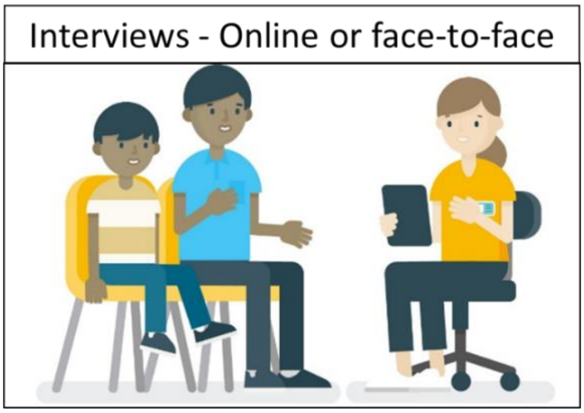
All families who take part in the study will have access to educational material from our study website. If your child tests positive for antibodies, you and your family will also be invited to an education session to help you understand what this means for your child's future. The education sessions will be held online and/or in-person. The education session will tell you about:

- The signs and symptoms of type 1 diabetes to look out for.
- Monitoring programmes (INNODIA: https://www.innodia.eu/) your child could enter, for frequent check-ups e.g. a blood test every 6 months.
- Research studies your child may be eligible for, testing new treatments that could delay the start of type 1 diabetes (with your consent).
- Families who attend the education session will be asked to complete a final study questionnaire afterwards



Step 6 – Interviews

- Parents can then take part in an interview study, to tell us how you found the screening programme and suggest areas for improvement.
- We want to hear from parents of children who have received positive or negative screening results.
- The interview(s) will be audio-recorded. Parents can choose if they want to take part in these or not. You can consent for the interview study at the end of the screening programme.
- The interview can be held at a convenient time for you on Zoom, by telephone call or in-person. You can stop the interview or take a break anytime.
- The study team will let you know if you have been selected to come for interview. We are sampling to ensure we have diverse representation.

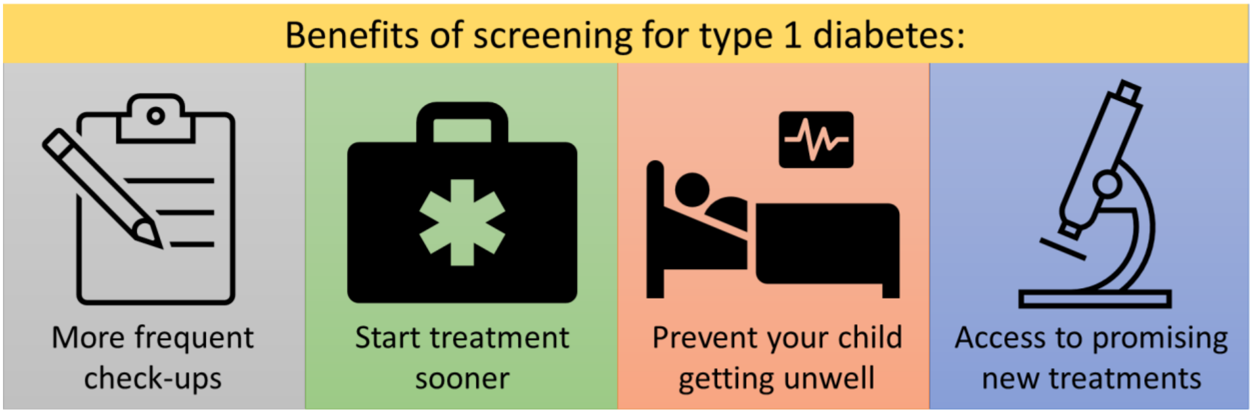


Who can take part in the ELSA study screening programme?

- Children aged 3-13 years can take part in the ELSA Study screening programme.
- Children with a diagnosis of type 1 diabetes are not eligible to take part in the ELSA Study.

What are the benefits of taking part in the ELSA study screening programme?

In this study, you can find out your child's risk of developing type 1 diabetes in the future. For children who are at high risk, finding out early gives us the chance to follow them up closely and start treatment sooner, before they become unwell. There is also the chance to enter research studies, testing promising treatments to delay the start of type 1 diabetes. This is not possible without screening.



The earlier we screen, the more opportunity we have to intervene.

What are the risks of taking part in the ELSA study screening programme and how will we reduce these risks?

Risks from taking part in the ELSA study	**How will we reduce these risks?**
Causing my child discomfort from the blood tests.	• The finger stick blood test is quick and easy. • We will only do the venous blood tests if we need to. • We will use numbing creams and experienced professionals will minimise the discomfort for you and your child.
Finding out my child is at high risk.	• The ELSA Study team are available to support families with this information and will explain what the next steps are.
No screening test is 100% accurate.	• The screening test used in the ELSA Study has been validated and undergone rigorous testing. • Monitoring is important to look at these antibodies over time.
Why screen when there is no cure?	• We are working towards preventative treatments, and are looking to find children at high risk to help them and other children in the future.
The questionnaire and interview may include sensitive topics.	• The ELSA study team will support you with these and you can choose to stop the questionnaire or the interview or take a break from them at anytime. The ELSA study team can refer you to your GP if we felt this would be helpful to further support your family.

What if I do not want to take part in the ELSA study screening programme?
Taking part in the screening programme is entirely voluntary and if you choose not to take part in the screening programme, this will not affect yours or your child's routine care in anyway. However, parents/guardians can still take part in the ELSA study interview, to tell us your thoughts and concerns about screening for type 1 diabetes. Your views will not be judged or challenged; we really want to hear a wide range of perspectives. You can let us know on the eligibility form if you would like to do the study interview only and then we will take consent for this and arrange the interview at a convenient time for you.

Who can take part in the ELSA study interviews?

- Parents with a child aged 3-13 years can take part in the interview study.
- Up to 2 parents/guardians can take part in the interview.

How do I register to take part/how do I enrol on the ELSA study?

Taking part is a three step process and you can complete these 3 forms online, in-person or by post:

- Step 1 – Eligibility form – tell us here if you want your child to do the screening programme,
- Step 2 – Consent Form(s). You can decide if you want your child to also complete an assent form.
- Step 3 – Personal and clinical details form.

The online consent process is via REDCap forms. If you prefer in-person or postal, please contact the study team by email or phone. You can choose home testing or community testing (we will provide you with instructions and support for either option).

What if there is a problem?

- If you have any concerns about the study, please contact the study team: elsa@contacts.bham.ac.uk.
- If you are unhappy with their response or wish to make a complaint, you can contact the sponsor's independent representative Dr Birgit Whitman on researchgovernance@contacts.bham.ac.uk.
- If you have any concerns about your data or wish to make a complaint about the way your data was handled, you can contact the University of Birmingham's Data Protection Officer on Dataprotection@contacts.bham.ac.uk

Data management:

You and your child's data will be stored confidentially in line with the Data Protection Act 2018 and General Data Protection Regulations (GDPR). We will keep all information about you safe. Your personal details will be stored securely in the REDCap database. Postal forms will be filed in a secure and locked office. Your child's screening test samples will be transferred from the Birmingham Children's Hospital Clinical Research Facility to the University of Birmingham Clinical Immunology Service, where these samples will be stored for the duration of the study and 10 years following this. Your child's screening result will be stored on NHS clinical systems (with your consent).

You can choose to consent to the following parts of the ELSA study (these are optional and not required for your child to take part in the ELSA study):

- Using your child's anonymised samples for further research studies, around the world for collaborative, ethically approved research.
- Contacting you about the qualitative interviews at the end of the study.
- Contacting you about future research studies your child could take part in, relevant to their screening test results.
- Providing us with your child's NHS number for long-term follow-up (10 years) of your child's medical records – this follow-up will not require any contact or appointments for you or your child.

What personal information do we need for the study?

We will need to collect the following information from you and your child for this study:

- Name of parent/guardian, legal guardian status e.g. birth mother, step-mother, your contact details (email, phone number and address) and your age, ethnicity, gender and occupation.
- Name, age, ethnicity and gender of your child.
- Family history of type 1 diabetes and if your child has coeliac disease or thyroid disease.
- Your child's GP contact details – this is to inform your child's GP of their screening test result.
- Your child's NHS number – this is optional and will be used for longer term follow-up with your consent. This helps us to understand the impact of screening for type 1 diabetes.

We will use this information to do the research or to check your data to make sure the research is being done properly. Your child will be assigned a code on entry into the ELSA Study. The study team will process and analyse data from the study using these codes rather than your child's personal details. Study team members who do not need to know who you are will not be able to see your name or contact details.

We have a data sharing and confidentiality agreement with Firetext and DOCmail. We are using Firetext to send you text messages to inform you about the study processes and if your child has a negative antibody result; this means, we will share your mobile phone number with Firetext with your consent. We are using DOCmail to send a letter with your child's results to their GP; this means we will share your postal address with DOCmail with your consent. The Firetext and DOCmail systems are GDPR compliant and subject to robust security processes. Data is held within an integrated platform and will never be shared with third parties within or outside of the UK.

You can choose to consent to the ELSA study team sharing your contact details with INNODIA so that they can provide you with details of monitoring programmes your child is eligible for. You can also choose to consent to the ELSA study team following-up your child's data through their medical records and the INNODIA monitoring programme. This will help us understand the long-term benefits of screening.

The audio transcripts from the study interviews, will be transcribed by an external provider (AD transcription services), with whom the University of Birmingham has a contractual and data processing agreement in place. Transcripts will be coded after checking the transcription for accuracy.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study. The anonymised data will be published at international scientific meetings/journals, but this will all be anonymised. If you agree to take part in this study, you will have the option to take part in future research using your child's data and samples saved from this study. We will ask you on the consent form if you agree to this.

What are your choices about how we will use your information?

You can stop being a part of the study at any time, without giving reason, but we will keep information about you that we already have. This is because we need to manage your data in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

- On our website: www.elsadiabetes.nhs.uk.
- By emailing elsa@contacts.bham.ac.uk or phoning us on: 0121 414 7814.
- By sending an email to the University of Birmingham's Data Protection Officer at dataprotection@contacts.bham.ac.uk.

Frequently Asked Questions:

1. **Who is leading and funding the study?** The ELSA study is being led by the University of Birmingham, and funded by Diabetes UK and the Juvenile Diabetes Research Foundation. The Study's Principal Investigators are Professor Parth Narendran and Professor Timothy Barrett.
2. **How have patients and the public been involved in this study?** We have worked with parents and young people to inform the design of our study.
3. **Who has reviewed this study?** This study is sponsored and insured by the University of Birmingham. The study has been reviewed and given a favourable opinion by an independent NHS research ethics committee, Wales REC 4.
4. **Are there any financial costs to me for taking part, and are there any rewards or payments for taking part in this study?** We will reimburse any reasonable travel expenses you incur for this study, once we have received evidence of your travel. If you prefer to receive and complete the physical paperwork, we will send you the forms and provide pre-paid envelopes for you to return them to us. There are no rewards for participation in this study, but we are very grateful to the families who take part in this study and give their time to support our research.

What happens next if you want to take part in the ELSA study?

1. Complete the 3-step online consent process or contact us for postal or in-person options, by email: elsa@contacts.bham.ac.uk or by phone: 0121 414 7814.
2. Visit our study website: www.elsadiabetes.nhs.uk for more information.

Further information

This study has been reviewed by the Wales REC 4 Research ethics committee.
The University of Birmingham is the Sponsor of the study.

Thank you for your interest in the ELSA study.