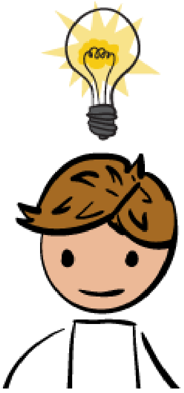
Hospital LOGO

MELD-ATG: Minimum effective low dose of ATG in people recently diagnosed with Type 1 diabetes

Participant Information Sheet (ages 5-10)

We want to tell you, and your mum, dad or the grown-up who looks after you, about a study called MELD-ATG.



Doctors need to work with children like you who have just been told that they have Type 1 diabetes, to help them answer questions about diabetes.

We still do not know how to stop diabetes.

But we are trying to find a way to stop it from happening or to make it better.

Would you like to help us with our research study to find out if taking a certain amount of medicine, called 'Anti-Thymocyte Globulin' (ATG), can help your body make small amounts of its own insulin for longer?

What is the MELD-ATG study?

You were told not long ago that you have diabetes and you need to take insulin to stop your blood glucose levels from going too high. Did you know that your body can sometimes make its own insulin for up to 2 years after you were first told you had diabetes?

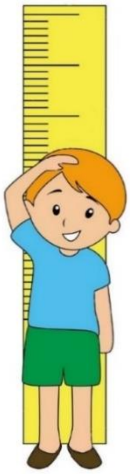
Doctors in your hospital are asking children like you if they would be happy to come to the hospital for 2 days to have a drip with the medicine in it. This might be like when you first came to the hospital when you were told you have diabetes and had to have some liquid given in a drip.

What will happen if I take part in the MELD-ATG study?

If you decide to join the study, and your mum, dad or the grown-up who looks after you, are happy for you to join, we will ask you, and your mum, dad or the grown-up who looks after you, to sign a form.

There are 10 hospital visits as part of this study. When you arrive at the hospital for each study visit the nurse or doctor will ask you, and your mum or dad or the grown-up who looks after you, some questions about how you are.

We will listen to your heartbeat and your breathing. Check your temperature, your blood glucose levels and the amount of insulin you take and then, measure your height and weight.



We will also need to take a small amount of blood from your arm. We do this by putting a very small plastic tube (called a cannula) into a vein in your arm.

We don’t want this to hurt you, so we can put some special numbing cream on your arm, or we can use a cold spray, to stop it from hurting so much.

For some of your hospital visits you will be able to have your breakfast before coming but other times you will not be able to. But it is important that you have a drink of water when you wake up on those mornings.

This is because we would like to do a special test called a ‘MMTT’. A ‘MMTT’ stands for a Mixed-Meal-Tolerance-Test. This is where you will have a special ‘milkshake’-type drink instead of your breakfast.

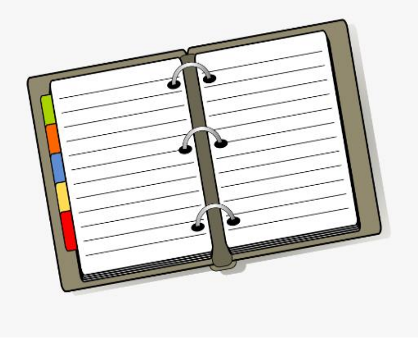
We will also need to take some small samples of blood at different times during this test, from the cannula in your armWe will explain to you, and your mum or dad or the grown-up who looks after you, what to do on these mornings with your insulin.

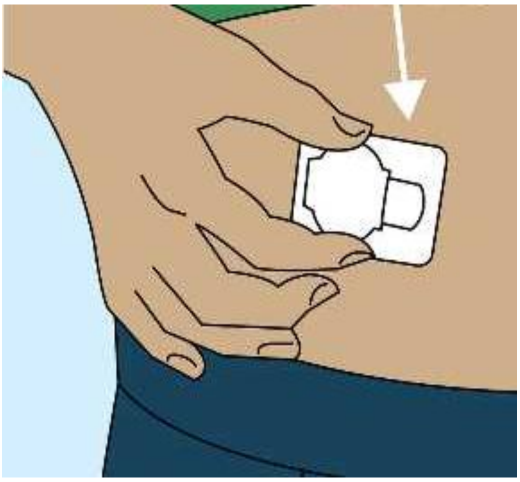
The MMTT takes about 2 hours, so you will have a bed to sit or lie on during the test so you are nice and comfortable, and you can watch TV, play games or read or even do some homework.

You will always be given something to eat and drink after the MMTT and be able to go to school in the afternoon.

When you have the ‘ATG’ medicine, you will be at the hospital for 2 days. You might need to stay in the hospital the first night, because it will be too late to go home. So, remember to bring your favourite games, books or toys (even your favourite pillow), and your mum or dad or the grown-up who looks after you will always be able to stay with you.

After having your ATG medicine at the hospital, you and your mum, dad or the grown-up who looks after you will be given a diary to fill in at home about how you are feeling. We will explain to you, and your mum, dad or the grown-up who looks after you, how to do this.





You might already have one, but if not, you will be given a Continuous Glucose Monitor (CGM) to use at home after having the ATG medicine. This is a special gadget that records your glucose measurements all the time (day and night) by having a tiny little tube put under your skin, usually on your tummy.

We will use the numbing cream or cold spray again before we put it on. We will show you, and your mum or dad or the grown-up who looks after you, how to use the CGM before you go home.

When you are at home, we will ask you to do a finger prick once a month and place a drop of blood onto circles on a special white card.

This is called Dried Blood Spots, or ‘DBS’ because it’s easier to say!

We will teach you, and your mum or dad or the grown-up who looks after you, how to do this. Most people do this at the weekend.

You may be surprised that sometimes we will ask you to bring some of your ‘wee’ and a small amount of your ‘poo’ to your hospital visits, but it can be used for tests.

We will give you special pots to put the wee and poo in and we will explain how to do this to you, and to your mum or dad or the grown-up who looks after you.

When you have finished reading about this study it would be a good idea to talk with your mum or dad or the grown-up who looks after you, or to the nurse or doctor before you make up your mind.

It is always a good idea to ask questions, if you are not sure about anything.

You may decide that you don’t want to join the MELD-ATG study, and it is OK to say NO, even if your mum and/or dad and/or the grown-up who looks after you are really keen for you to do it. It is also OK to say YES, and then change your mind later.

Thank you very much for reading about the MELD-ATG study

Study Doctor:

Address:

Study Nurse(s):

Telephone Numbers:

Email:

Hospital LOGO

Participant Identification Number: Study ID

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ASSENT FORM - AGES 5-10

Principal Investigator: ____

If you agree, please circle boxes

1. Have you read (or had read to you) information about this study?	☺ Yes	☹ No
2. Do you understand what the study is about?	☺ Yes	☹ No
3. Have you asked all the questions you want?	☺ Yes	☹ No
4. Have you had the questions answered in a way that you understand?	☺ Yes	☹ No
5. Do you understand that it is OK to stop taking part at any time?	☺ Yes	☹ No

6. Would you like to take part? (please, circle only one)	
	

If you would like to take part, please write your name below:

Name:____

Date:____

Name of Person taking Assent:____________________________________

Date:____________ Signature:__________________________________

Role of Person receiving Assent:__________________________________

**1 copy for participant; 1 copy for researcher site file; 1 (original) to be kept in medical records.*