

Study Title: Early genomic testing for Inherited Bleeding Disorders in patients without a diagnosis after first line testing: a randomized controlled trial

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What is a research study?

A research study is a way to test new ideas to see if we can do things better. This research study is a way to learn more about inherited bleeding disorders, a group of diseases that cause bleeding. You do not need to be in a research study if you don't want to.

Why am I being asked to be in this study?

You are being invited to take part in this research study because we are trying to learn more about diseases that cause bleeding and how to diagnose them. We are inviting you to be in the study because you have had problems with bleeding or bruising OR because some of your family members have problems with bleeding or bruising.

We know that some health problems are caused by changes in genes. A gene is something that is in each cell of the human body. Genes carry the information that decides what is passed to you from your parents, like the colour of your eyes and hair. Genes also seem to be important for understanding why bleeding problems occur more in some families than in other families. In our study, we will try to find the gene which causes your problems with bleeding or bruising.

Who will know I am in this study?

This study was explained to your parents/guardians and they said that we could ask you about the study. Your parents/guardians can help you decide if you want to be in this study.

Only the research team and your parents/guardians will know that you are in the study. There may be times where your family doctor will need to know test results performed by this study, for example if you are diagnosed with a bleeding disorder.

If I join this study what do I need to do?

We want to tell you some things about this study. If you agree to take part:

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- You will be in the study for 12 months
- We will use a needle to take some blood from your arm, called blood work. This will be done at the same time as your normal blood work, so it will only be one needle. We will just take one additional tube for the research study, about 1tsp
- We will use your blood sample to do genetic testing. This is how we will try and find the gene which is causing your bleeding or bruising.
- There will be around 20-50 other children in this research study
- We will ask you to answer some questions about your life, your feelings, if you have any pain, and how your bleeding might affect your life. If you have a period, we will ask you some questions about that. You can skip any questions that you don't want to answer.
- We will ask you the questions today, and then one year from today we will ask you to answer the questions a second time.
- We will ask to have access to your medical chart to review your health problems and the results of tests that are done.

Will any part of the study hurt or be scary?

Getting blood work done might hurt or be scary for you. There might be a small bruise where the needle was for a few days after.

You might not like answering some of the questions, they might make you feel uncomfortable. You can skip any questions you don't want to answer.

Will the study help me?

We think that the study might help you by figuring out why you have bleeding or bruising problems.

Will the study help others?

This study might find out things that will help us diagnose other children with the same bleeding or bruising problems as you. If other members of your family also have bleeding or bruising problems, it might help us diagnose them as well.

Can I say no?

Yes of course, you can decide not to be in the study. It's up to you. No one will be upset if you don't want to do this study. You can tell your parents, grandparents, guardians or your doctor if you do not want to be in the study. If you do join the study, you can change your mind and stop being part of it at any time.

What choices do I have if I say no to this study?

If you say no to this study, you will go through the regular steps of seeing if you have an

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inherited bleeding disorder. Your doctor will decide what tests need to be done.

You can ask us for more information about these other choices.

Who will see information about me?

The information collected about you during this study will be kept safe and your name will not be kept with this information. The people doing the research will be able to see the information collected about you. If you receive a diagnosis, this information will be given to your parents/guardians. Your parents/guardians will not see your answers to the questions unless you share it with them. The researchers will not tell your friends or anyone else if you decide to join the study or not. If the researchers think that you might need help then they will need to tell someone.

Other people doing studies in the future would have to ask special permission to look at your information. These researchers would not know your name either.

Do I get anything for being in the study?

You or your parents/guardians will get \$25 as a token of appreciation for answering the additional questions.

What if I have questions?

You can ask any questions you want about the study.

What if I have questions later?

If you have any question about this study that you didn't think of now, either you can call or have your parents/guardians call : Dr. Paula James the study doctor, at : 613 533 6329.

You will be given a copy of this paper to keep.

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Would you like to take part in this study?

Yes, I will be in this research study:

Child's name

Signature (if applicable)

Date

☐ Assent was obtained orally

I have discussed this research study with using language which is understandable and appropriate for the participant. I believe that I have fully informed him/her of the nature of the study and its possible risks and benefits. I believe the participant understood this explanation and assent to participate in this study.

Person obtaining Assent

Signature

Date