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## INFORMATION SHEET FOR MINORS (10-15)

# WHAT ARE THE EFFECTS OF HAVING AN UNUSUAL VALVE IN YOUR HEART?

We are asking whether you and your parents would be interested in taking part in a research study.

Before you decide if you would like to join in, it is really important that you understand what the study is about, why the study is being done and what it would involve for you. So please read and think about this leaflet carefully. Also talk to your family, friends, doctor or nurse about it if you want.

If something isn't clear or you have more questions you can ask your parents to give as a call and we can discuss it with you and your parents. Thank you for reading this.

### PART 1

#### Why are we doing this research?

This research is being done to try look at one of the heart valves, the aortic valve.



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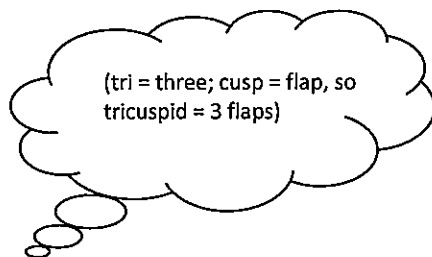
**Short Title:** OXBAV

**Ethics Ref:** 10/H0505/100

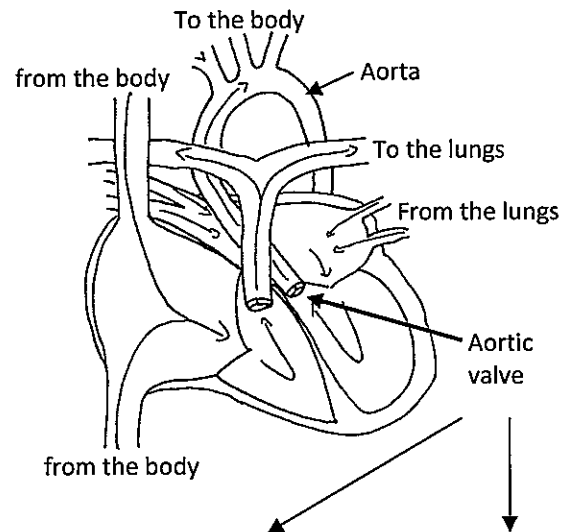
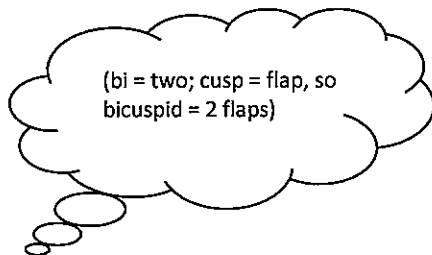
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- The heart has 4 valves to make sure that the blood is flowing in the right direction.
- Blood flows from the body – to the lungs – back to the body.
- The blood vessel coming out of the heart is called aorta.
- The valve between the heart and the aorta is called aortic valve.
- Most people have an aortic valve with 3 flaps = tricuspid aortic valve.



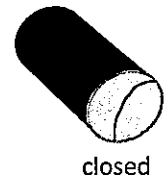
- Some people have an aortic valve with only 2 flaps = bicuspid aortic valve.



tricuspid aortic valve



bicuspid aortic valve



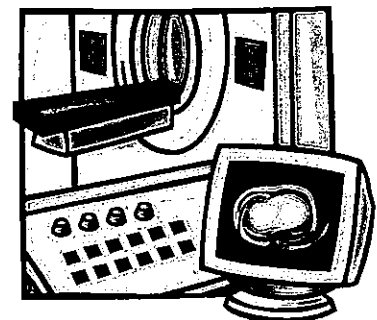
In this study we will look at children and adults with both types of valve.

We also know that other people in the family can have a bicuspid valve as well. Therefore we are also asking your family to take part in the study.

To take good pictures of your heart and blood vessels we use:

1. an ultrasound scan ("echo scan" or "jelly scan")
2. an MRI scan which is a gigantic body scanner shaped like a polo mint (see picture)

Both are completely harmless.



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### Why have I been invited to take part?

You have been invited because you or someone in your family has a bicuspid aortic valve (or a disorder which overlaps with this).

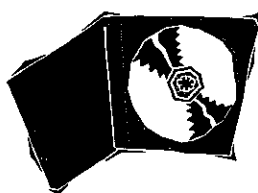
You would be one of at least 375 people, a mixture of children, young people and adults, helping us with this study.

### Do I have to take part?

No, you don't. It is your choice whether you want to take part and you can always change your mind.

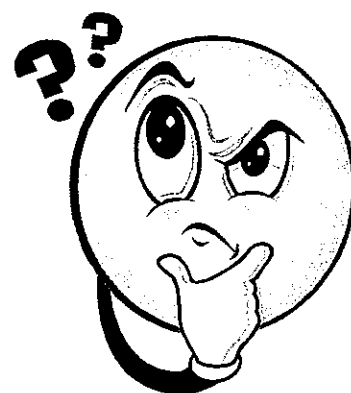
### What will happen to me if I take part?

We will invite you to the Oxford clinic with at least one of your parents and your favourite music CD.

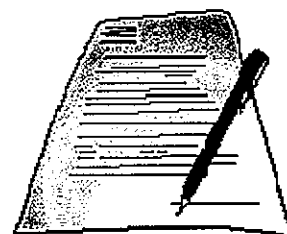


The entire research visit will take about 3 hours but can be split into two visits if you prefer.

At this visit you and your parents will have the opportunity to ask any further questions.



Then you and at least one of your parents sign a form that you are both happy for you to take part in the study.



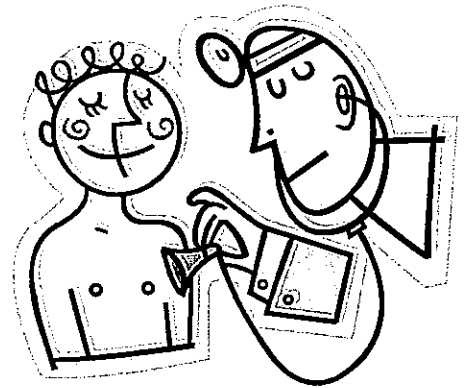
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Then we will:

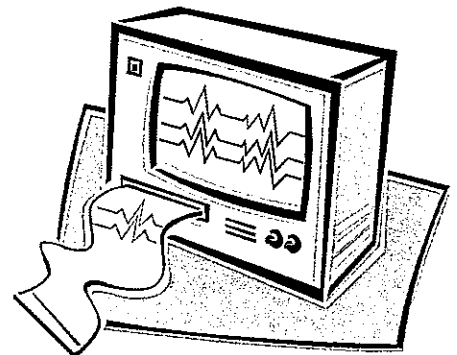
Ask about your health and medications.



Measure your height and weight and listen to your heart.



Take a trace of your heart with an ECG (electrocardiogram) machine.

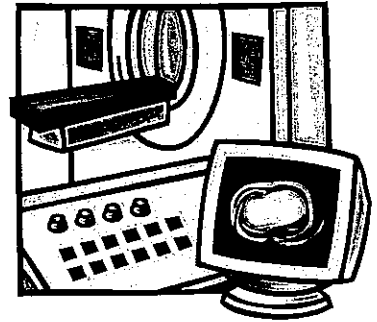


Do a "jelly scan" (Ultrasound scan) of your heart and arm while you can find "where's Wally" or "where's Stig" if you want to.



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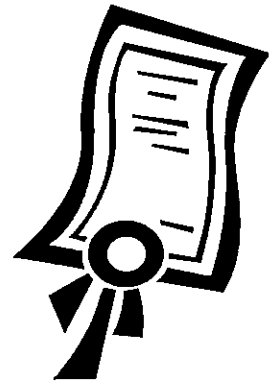
Do an MRI scan (the gigantic polo mint) of your heart on two different machines while you listen to your music. You need to lie still for this and at times we will ask you to hold your breath for a bit.



Ask you whether you would be happy to have a blood test with “magic cream” and more “where’s Wally” or “where’s Stig” distraction. But it’s okay if you don’t want a blood test.



Present you with a certificate for taking part and explain your scan pictures to you and your parents. After the visit you can do everything in your life as normal again.



Over the next five years we will then keep in touch with you and we will phone your parents every year.

After three and five years we will also invite you to come back for another visit just like this one. This is to check whether anything changes with time.

### What will I be asked to do?

On the morning of your tests we need to ask you not to have any breakfast. You can have water to drink. We will have some breakfast ready for you during the visit! After the visit you can do everything in your life as normal again.

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### **Will the measurements be uncomfortable or dangerous?**

If you choose to have the blood tests it can be a bit uncomfortable or give you a slight bruise. But we have “magic” cream or cold spray so it doesn’t hurt as much.

### **Is there anything else to be worried about when taking part?**

All measurements we choose are safe. The MRI scan is noisy but we will give you headphones to protect your ears so you can listen to your own music. You should not take part in this study if there is any chance you are pregnant.

### **Will taking part in the study help me?**

The study will not help you right now. It will increase our knowledge of what it means to have a bicuspid aortic valve.

### **What would happen if I found out that I have a bicuspid aortic valve that I did not know about?**

A senior doctor would discuss this with your parents and you. We would then make an appointment with the paediatric cardiology team (children’s heart doctor) in the outpatient clinic. If you are feeling fine you probably won’t need any treatment but the paediatric cardiology team would probably want to see you every few years.

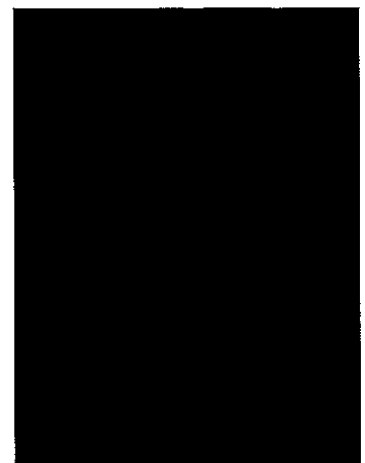
### **What do I do if I don’t want to take part in the research anymore?**

Just tell your parents and the people carrying out the research that you don’t want to take part anymore. You don’t have to give any reason. It is **YOUR** choice.

### **WHO SHOULD I ASK IF I HAVE FURTHER QUESTIONS?**

If you have any questions, talk to your parents first. You can also contact the research team in Oxford: Dr Malenka Gedicke or Dr Alex Pitcher by telephone on (01865) 221875 or email [malenka.gedicke@paediatrics.ox.ac.uk](mailto:malenka.gedicke@paediatrics.ox.ac.uk)

**Thank you for reading so far. If you are still interested please go to Part 2.**



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## PART 2: FURTHER INFORMATION

**This is more detailed information that you need to know if you are taking part**

### **What happens when the research project stops?**

The result of the study will be written up so that people can read about it but they won't know that you were in the study.

### **What happens if new information comes along?**

Sometimes in the time it takes to do the study new information comes up. If this happens, one of us will tell you and we will discuss whether you still want to continue with the study.

### **What if something goes wrong?**

If there is a problem you should talk to your parents first or any of the researchers.

### **Will my information be kept private? Will anyone else know that I am taking part?**

All your information will be kept private. We will only inform those who have a need or right to know like your parents and your GP.

### **What will happen to any samples I give?**

The blood sample that you give at your visit will be stored in a safe place. We will use the blood sample to do some tests which help to understand bicuspid aortic valves better. We might keep the samples in case more tests become available in the future.

### **Will any genetic tests be done?**

We might look at genes that will help us to understand how blood vessels work. We might also look for genes that both you and your family have to see whether any of them could cause bicuspid aortic valves.

### **Who is organising and funding the research?**

The study is being organised by the Department of Cardiovascular Medicine at the University of Oxford. The study is being paid for by the British Heart Foundation.

### **Who has reviewed the study?**

Before any research is allowed to go ahead it has to be checked by a group of people called the Research Ethics Committee. They make sure that the research is fair. This study has been reviewed by the Berkshire Research Ethics Committee.

### **Thank you for your time and thinking about taking part in the study**

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