

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: South African Paediatric Surgical Outcomes Study-2 (SAPSOS-2)

A South African multi-centre trial to assess the feasibility and clinical efficacy of preoperative oral iron to treat preoperative anemia in children undergoing elective noncardiac surgery

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Information:

You are being approached because your child may be able to be a part of a research study on anaemia.

The doctors that are part of this study are trying to find out if they can test children for anaemia in the hospital clinic and then treat the anaemia before the child has their operation. There will be a total of 420 children involved in this study.

What is Anaemia?

Anaemia means that the haemoglobin measured on a blood test is lower than normal. Anaemia in children having surgery is very common.

How can a Doctor tell if my child has anaemia?

This is done by pricking a finger or doing a blood test.

What causes anaemia?

There are different types of anaemia, but the commonest cause of anaemia is not enough iron in the body. This is known as iron deficiency anaemia. The doctors also want to test whether your child has anaemia because of too little iron.

Can anaemia be treated?

Yes, but at the moment the doctors only do a blood test the day before, or on the day of the operation. Unfortunately, this does not give the doctors time to treat the anaemia before your child has the operation.

Does it matter if my child has anaemia when they have their operation?

Yes, doctors think that anaemia can be a problem when a child has an operation. It may be more likely that your child will need a blood transfusion or have a problem after the operation. It is also very important to treat anaemia in children because it can cause problems with a child's development.

If I DO NOT AGREE for my child to be part of the study what will happen now?

Agreeing for your child to be part of this study is voluntary. You do not have to take part in order for your child to be treated at Red Cross War Memorial Children's Hospital. If you decide not to take part or if you change your mind later it will not change how your child would normally be looked after.

If I AGREE for my child to be part of this study what will happen now?

1. HOSPITAL CLINIC

The nurse or doctor will do a finger-prick test on your child now to check for anaemia.

What will happen if the finger-prick test shows that my child DOES NOT have anaemia?

Your child will have their surgery as planned and will not need any treatment for anaemia.

What will happen if the finger-prick test shows that my child has anaemia?

The nurse or doctor will take a blood sample to test for iron-deficiency anaemia. These tests will be sent to a laboratory to help doctors understand why your child has anaemia, and how many children having surgery in South Africa have iron deficiency anaemia.

Taking a blood sample may be uncomfortable and may cause a bruise. Before the blood sample is taken a small amount of numbing cream (EMLA) will be put on to the skin to make your child more comfortable when the sample is taken.

Will my child be treated for anaemia?

Doctors would like to treat all children with anaemia. At the moment doctors do not know for certain what is the best way to do this. The doctors want to find out if they can treat your child's anaemia by giving your child iron syrup or tablets to drink every day before their operation.

The doctors want to make sure the iron medication has the best chance of working. If your child has not been dewormed during the last 6 months, the doctor at the hospital clinic would like to give your child deworming medication.

2. AT HOME BEFORE SURGERY

The doctors would like to give you a 3-month supply of iron to take home and give to your child every day before they have their surgery.

It is very important that the iron medicine is stored in a safe place that your child, or other children cannot reach. Iron overdose can be very dangerous.

If you are worried that a child has taken an iron overdose please contact the Poison Information Helpline 24/7 emergency number 0861 555 777 immediately to find out whether you can monitor your child at home or need to take the to the clinic or hospital.

Appendix A

Some children may have side-effects from taking the iron medication. It is very important that you still try and give your children the medication every day, or it may not work” to “It is very important that you still try and give your child the medication and discuss how to deal with the side effects with the study team. If you are worried or want to ask any questions about the medicine or the study then please send an SMS or WhatsApp message to the research assistant (....., cell phone), and they will call you back. The research assistant will also call you once a week to ask you if your child has managed to take their medication, or if there were any problems with taking the medication.

3. WHEN MY CHILD IS ADMITTED TO HOSPITAL FOR SURGERY

When your child is admitted to hospital for their surgery everything will happen like it normally would. As part of their routine care, a finger-prick or blood sample will be taken to recheck the haemoglobin. Doctors often need to know the result before the operation, but the doctors will also do the blood test when you child is asleep during the operation if it is safe to do so.

Will I find out the results of the blood tests done as part of this study?

The doctor looking after your child in hospital will be able to tell you whether your child’s haemoglobin is now better, or whether your child needs further tests or medicine to treat anaemia.

Information collected

If you agree for your child to be part of this study, the doctors will collect the following information which is routinely written down as part of your child’s standard patient care during the clinic visit:

- Basic information about your child including age, sex, weight and height.
- Medical information including other illnesses your child may have, if your child takes other medicine at home, the reason you child needs surgery, and the type of surgery your child will have.

This information will be kept both on paper and on computer. To protect your child’s privacy, the information will be labelled in a way that will not identify your child. If the results of these studies are published, you and your child’s identity will be kept confidential.

By signing this form, you are allowing the use of this information for the research study. This research project has been approved by the University of Cape Town’s Human Research Ethics Committee. If you have any ethical concerns or questions about you or your child’s rights or welfare as a participant in this research, the Human Research Committee can be contacted on 021 406 6338.

Please read this form carefully and ask the investigator (study doctor) to explain any words or information that are not clear to you. This will help to make sure you understand what you and your child will need to do before you agree for your child to be part of the study. You will be given a copy of this consent form to take home with you. The nurses and doctors will answer any questions you may have about this consent form and about the study.

CONSENT STATEMENT

I officially confirm that:

- I have read the above information form and understand that the study involves research.
- I understand that the doctors will make a copy of some of my child's routinely recorded data.
- I understand that my child will have a finger-prick to check for anaemia.
- I understand if my child's finger-prick test shows that they have anaemia that a blood sample will be taken from my child.
- I understand that my child will be given deworming medication if they have not been dewormed in the last 6 months.
- I understand that if my child has anaemia, I will be given iron and vitamin C medication for my child to take every day before surgery.
- I have had the chance to ask questions. All my questions have been answered to my satisfaction.
- I understand that any information that leaves the doctor's office will be de-identified (i.e., identifying information will be removed from the documents).
- **I understand that iron overdose is very serious and that I must phone 0861 555 777 for help immediately**

Yes

No

Name of child (participant) (printed)

Parent/ Legal Representative's name (printed)

Signature

Date

Name of person obtaining consent (printed)

Signature

Date

Name of interpreter (printed)

Signature

Date

ASSENT FORM FOR MINORS

TITLE OF THE RESEARCH PROJECT: South African Paediatric Surgical Outcomes Study-2 (SAPSOS-2).

RESEARCHERS' NAME(S): Dr. Heidi Meyer

RESEARCHER'S CONTACT NUMBER: 0799988858

What is RESEARCH?

Research is something we do find **NEW KNOWLEDGE** about the way things (and people) work. We use research projects or studies to help us find out more about children and teenagers and the things that affect their lives, their schools, their families and their health. We do this to try and make the world a better place!

What is this research project all about?

When children come to hospital for an operation the nurses or doctors do a blood test. Sometimes one of the results on the blood test is lower than normal. This is called anaemia and doctors know if children have anaemia they may have more problems when they have an operation. Doctors think that it will help if they can give children medicine before they have their operation to make their blood test better.

Why have I been invited to take part in this research project?

Because you are going to have an operation.

Who is doing the research?

The doctors at the hospital.

What will happen to me in this study?

The nurse or the doctor is going to do a finger-prick test. This can be a little bit sore, but it is very quick. If the test result on the finger-prick is lower than normal, then the nurse or doctors will do a blood test. This is what happens when you have a blood test:

- (1) Before the needle, a big rubber band that feels like a balloon will be wrapped around your arm. The band will feel tight like someone is squeezing your arm.
- (2) The nurse or doctors will clean a small patch of skin on your arm, and this will feel cold.
- (3) The needle will be put into the arm and blood will flow into the tube. You will feel a pinch or prick that can sting or hurt a little, or you may feel nothing at all.
- (4) Once the blood is taken, the needle comes out and a small bandage is put on the spot where the needle was.

The nurse or doctors will then give you some medicine to take at home every day before you come to hospital for your operation.

Can anything bad happen to me?

Taking a blood sample may be sore and may cause a bruise.

Sometimes the medicine can make your tummy sore. The doctors will call on the telephone every week to ask if you are okay or if the medicine has made your tummy sore.

Appendix B

Can anything good happen to me?

Doctors think that it will help if they can give children medicine before they have their operation to make their blood test better.

Will anyone know I am in the study?

The nurses and the doctors at the hospital looking after you will know you are in the study, but there are lots of children in the study. Afterwards your name will not be used and no-one else will be able to tell you were in the study.

Who can I talk to about the study?

If you are worried or want to ask any questions about the medicine or the study then you can ask questions now or you can talk to the research assistant (TBC, cell phone TBC).

What if I do not want to do this?

Some children do not want to take part in this study, and that is okay. It is also okay to say you want to stop being in the study at any time without getting in trouble.

Do you understand this research study and are you willing to take part in it?

 YES NO

Has the researcher answered all your questions?

 YES NO

Do you understand that you can STOP being in the study at any time?

 YES NO

Signature of Child

Date