**KEMRI Wellcome Trust Research Programme: Patient Information and Consent Form**

**First-Line Antimicrobials in Children with Complicated Severe Acute Malnutrition**

*(Trial participant)*

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| **Institution** | **Investigators** |
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| Coast General Hospital, Mombasa, Kenya | Victor Bandika, Jones Makori Obonyo, Laura Mwalekwa, John Odhiambo, Fauzat Hamid |
| Mbagathi Hospital & University of Nairobi, Kenya | Christine Manyasi, Molline Timbwa, Joshua Wambua |
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**LAY TITLE: A study to compare antibiotics used to treat children with severe malnutrition.**

*Introduction*

Your child is being admitted to hospital because they are sick. He or she has been examined by the study team and also found to have malnutrition. Your child will have a blood test done to check their general health, and will be given antibiotics to treat infections that are common in children with malnutrition. These tests and treatment are part of the normal care for a child with malnutrition.

*Who is carrying out this study?*

This study is being carried out by KEMRI in Kenya and Mbale Hospital in Uganda in collaboration with University of Oxford, UK. KEMRI is a Kenyan government organization that carries out medical research to find better ways of preventing and treating illness in the future for everybody’s benefit.

*What is this study about?*

In this study we want to find out which antibiotics that are given to treat infections in children admitted with malnutrition are most effective. We will be looking at two different types of antibiotics that are used: i) those that are given by injection and ii) an antibiotic that is given orally. Children who are enrolled in this study will participate in investigation of both the injectable and the oral antibiotics.

All children with severe malnutrition who are admitted to hospital are treated with antibiotics by injection because they often have serious infections. In this study, children will receive one of two different types of antibiotic treatment by injection.

* The usual current treatment that uses two drugs: penicillin and gentamicin
* An alternative treatment that uses one drug: ceftriaxone

Children with severe malnutrition are also sometime treated with an oral antibiotic to clear gut infections, but we are not sure if it is helpful, and some hospitals use it and some don’t. In this study, children will also receive one of the following:

* Metronidazole (often known as Flagyl)
* A similar liquid that does not contain an antibiotic.

All of the antibiotic drugs being used in this study are widely used and already licenced for use in children in Kenya and Uganda *[sites to delete as appropriate].*

In this study we will ask 2000 children admitted with severe malnutrition to participate. The decision on which child gets which drugs will be decided by a system based on chance, without any preference. All participants will have the same chance of receiving any of the treatment arms.

We will find out if there is any difference between the treatment groups by closely watching the progress of everyone in the study. To make sure that the findings of this study are as accurate as possible it is important that no one knows which child is receiving which oral medication until the end of research. We are asking your permission for your child to participate in this study.

*What will it involve for me/my child if I agree?*

If you agree for your child to participate, we will first assess their clinical status by taking body measurements, asking you questions about their health and factors that might contribute to their illness, as well as examining them.

In addition to the blood tests taken as part of the normal admission procedures, we will take an additional small amount of blood from the child’s arm at the same time that samples are taken as part of your child’s normal treatment. The extra amount taken for research will be half a teaspoon (2.5 ml). The same volume of blood will be taken should a child be readmitted before the end of the study period. We will also take two small faecal samples using a soft cotton wool swab for research. Other samples to be taken after the initiation of treatment are as follows:

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| --- | --- |
| **Number of days  after enrolment** | **Sample to be collected** |
| At admission | 2 small faecal samples taken using a soft cotton wool swab & one sample of whole faeces & half a teaspoon (2.5ml) of blood |
| At discharge | 2 small faecal samples taken using a soft cotton wool swab & one sample of whole faeces & half a teaspoon (2.5ml) of blood |
| 45 days | 2 small faecal samples taken using a soft cotton wool swab & one sample of whole faeces |
| 90 days | 2 small faecal samples taken using a soft cotton wool swab |
| Readmission to hospital | Half a teaspoon of blood (2.5ml) taken at admission in addition to the usual investigations undertaken to help treat your child & 2 small fecal samples taken using a soft cotton wool swab |

There will be scheduled study visits following the initiation of treatment; on days 14, 45 and 90 after today. At these scheduled visits the following will be done: body measurements (weight, circumference of the arm and height); clinical assessment; and collection of information on their health progress. Collection of the small faecal sample using a soft cotton wool swab will not hurt your child.

Whilst your child is in hospital and at the scheduled follow up visits we may also ask you questions about the costs that you and your family have encountered as a result of the hospitalisation and any outpatient care that your child receives. If your child does not attend the follow up visits, we will contact you by phone and may need to visit your home to find out about your child.

*Are there any risks or disadvantages to me/my child of taking part?*

Our priority for every participant is their well-being. The antibiotics that will be given in the study are already regularly used routinely in hospitals. Some of the side effects that have been associated with them include: loss of appetite, abdominal discomfort, diarrhoea, vomiting, skin rash and very rarely an allergic reaction.

The amount of blood taken is too small to affect your child’s health. Taking blood from the arm causes a small amount of pain, bruising, swelling, discomfort and a very small chance of infection. If this happens, we will provide treatment. We will use a careful procedure to help prevent these. If your child needs further blood tests as part of their care, these will be done at the same time. Use of a swab to collect faecal samples poses very low risk to your child. If your child has diarrhoea and their stools need to be tested to inform treatment, we will do that separately.

An independent committee will monitor this research continuously to ensure participants safety and rights are respected at all times. If for any reason the doctors looking after your child think they would benefit from leaving this trial, they will recommend this and ensure that you receive the normal treatment given to people who are not in the trial.

You will be asked to bring your child back for follow up at the clinic on specific days, and we will pay for the costs of your transport, but only for these scheduled study visits. As well as transport costs, we know that these follow up visits will take some of your time. We will therefore compensate you with for lost earnings for each scheduled study visits that you attend. This will be according to national recommendations: Ksh 300 at rural sites and Ksh 500 at urban sites *[sites to delete as appropriate]*.

This research is supported by University of Oxford who will pay for any treatment or compensation in the unlikely event of any injury resulting from participation in this study.

*Are there any advantages to my child of taking part?*

Your child will be reviewed daily by one of our study clinicians, together with the regular hospital staff. The study is supporting additional training and staffing for the children’s ward for this hospital. We will provide alternative antibiotics at no cost (according to recommended antibiotic guidelines) if they are needed and ensure that your child is referred to nutrition clinic and other clinical services on discharge, as needed. We will pay the costs of your child’s inpatient stay for this admission and any re-admission to this hospital. We will also pay for any consultations and investigations that are available in this hospital. There is no other direct benefit to you in participating, but you will also be helping us to improve care for children who have malnutrition in the future.

*What happens if I refuse to participate?*

All participation in research is voluntary. You are free to decide if you want your child to take part. Your child will still receive the recommended standard of care if they do not take part. No blood samples for research will be taken, but the clinicians may still wish to test your child’s blood in the usual way for their care. If you do agree you can change your mind at any time and withdraw your child from the research. This will not affect your child’s care now or in the future.

*What happens to the samples?*

All the information and samples collected will be held confidentially. Individual names are removed from all samples and replaced by codes, so that samples can only be linked to the children by people closely concerned with the research. Most of the research tests that will be done on the blood and faecal samples will be done in Kilifi or Nairobi. However, some tests to better identify any bacteria found cannot be done in Kenya, so part of the samples will be sent to the University of Oxford or the London School of Hygiene and Tropical Medicine, UK. After the research, a small portion of the blood and stool samples will be stored. We would like to store them for up to ten years. In this time, new research about children’s health relating to the objectives of this study may be done on these samples. This is expected to involve using new ways of looking for infection. All such research must first be approved by a national independent expert committee to ensure your safety, rights and privacy are respected.

*Who will have access to information about me/my child in this research?*

All our research records are stored securely in locked cabinets and password protected computers. Only a few people who are closely concerned with the research will be able to view information from participants.

In future, information collected or generated during this study may be used to support new research by other researchers in Kenya and other countries. In all cases, we will only share information with other researchers in ways that do not reveal individual participants’ identities. For example, we will remove information that could identify people, such as their names and where they live, and replace this information with number codes. Any future research using information from this study must first be approved by a local or national expert committee to make sure that the interests of participants and their communities are protected.

*Who has approved this research?*

All research at KEMRI has to be approved before it begins. An independent national committee, an international committee and a committee in Kilifi have looked carefully at this work and agreed that the research is important, that it will be conducted properly and your safety and rights have been respected.

*What if I have any questions?*

You are free to ask questions of any staff at any time. You can also contact the research team using these contacts:

*Dr Caroline Ogwang, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 0729 950260 or 0722 203417, 041 7522063*

If you want to ask someone independent about this research please contact:

*Community Liaison Manager, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 041 7522 063, Mobile 0723 342 780 or 0705 154 386*

and

*The Secretary - KEMRI/Scientific and Ethics Review Unit, P. O. BOX 54840-00200, Nairobi, Tel number: 020 272 2541 Mobile: 0722 205 901 or 0733 400 003 email: seru@kemri.org*