KEMRI Wellcome Trust Research Programme: Patient Information and Consent Form

(version 1.0 5th June 2020- English.)

STUDY TITLE: **Gastroenteritis Rehydration Of children with Severe Acute Malnutrition. (GASTRO-SAM)**

LAY TITLE: **Giving fluids to children admitted with Malnutrition and diarrhoea.**

Institution	**Investigators.**
KEMRI Kilifi	Mainga Hamaluba, Nchafatso Obonyo, Hellen Mnjalla
KEMRI $Imperial college UK	Kathryn Maitland.

You are being asked to allow your child to take part in a research study. The box below tells you important things you should think about before deciding/allowing your child to join the study. We will provide more detailed information below the box. Please ask questions about any of the information before you decide/allow your child to participate. You may also wish to talk to others (for example, your family, friends, or your doctor) about this study, before agreeing to join.

Key Information for You to Consider.

Voluntary Consent. You are being asked to allow your child to volunteer for a research study. You can choose whether you would like your child to participate or not. 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.

Purpose. In this study, we aim to find out what is the best way to replace fluid losses among children with severe malnutrition, whether we need to replace the fluid losses orally or through the veins either rapidly or more slowly. We also intend to find out for those with moderate dehydration (following resolution of severe dehydration), whether the currently recommended solution ResoMal is better than standard ORS which is the solution used in those without severe malnutrition.

Duration. Your child's participation in this study will last 1 month from the time they are enrolled.

Procedures and Activities. If you agree for your child to participate, for those with severe dehydration they will be allocated to receive either;

- Fluids through the vein (usually given to those without severe malnutrition) which is given quickly over 3-6 hours depending on age with extra fluid given where necessary.
- Slower where the same volume is given over 8 hours and no extra fluids allowed.
- Rehydration with ORS with fluids given only when they have danger signs.

For those with moderate dehydration, and the initial group after rehydration, they will be allocated to receive either ORS or ResoMal (Oral fluids)

We will also collect approximately 1 tablespoon (9.5mls) of blood during admission for research and an additional 3mls during follow up visits.

Risks or disadvantages. There are no known risks since the rehydration fluids being used are already tested to be safe and are currently being used. Taking blood from the arm causes a small amount of pain, *swelling, discomfort and minimal chance of infection*. If this happens, we will provide treatment, the amount taken is too small to affect your child's health.

Inserting a tube for collecting urine and in some cases a tube through the nose into the stomach involves a small amount of pain and discomfort during the procedure, and a minimal chance of infection.

Benefits. There are no direct benefits in this study. However, by taking part your child may help us improve the care of children who have serious dehydration and severe malnutrition in the future.

Alternatives. If you choose not for your child to participate s/he will still receive treatment as per the standard guidelines. You are also free to withdraw your child from the study at any time.

Introduction:

Your child has been examined by the doctor and found to have severe malnutrition plus signs of severe fluid loss (called dehydration) as a result of an illness which causes diarrhoea and vomiting called gastroenteritis. We need to admit your child to hospital, take some blood tests and treat them to replace these losses. Currently the country is following the World Health Organization (WHO) recommendation of giving Oral rehydration solution (ORS) and ONLY giving fluids through the veins for those with danger signs. WHO also recommends fluids through the veins if the patient cannot take oral fluids..

Who is carrying out this study?

This research is being carried out by KEMRI. KEMRI is a 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 research we aim to find out what is the best way to replace the fluid losses, whether we need to replace the fluid losses orally or through the veins either rapidly or more slowly. We also intend to find out for those with moderate dehydration (following resolution of severe dehydration), whether the currently recommended solution ResoMal is better than standard ORS which is the solution used in those without severe malnutrition.

We aim to enroll 200 participants in Kilifi county hospital and two other sites in Uganda (Mbale regional referral hospital and Soroti regional referral hospital).

What will it involve for me/my child

Participants will be selected depending on how they present (Group A with severe dehydration, Group B for those with moderate dehydration to one of three options below:

<u>Group A</u>

i) Rapid fluids by a drip using 100mls/kg of a fluid called Ringers Lactate over 3-6 hours (Experimental)
ii) A slower rehydration by drip (100 mls/kg Ringers Lactate) given over 8 hours (Experimental)
iii) WHO rehydration regime: ORS and with the drip (Fluids through the vein) being used for those with danger signs. (standard of care)

<u>Group B</u>

Following resolution of severe dehydration and for those with moderate dehydration, the participants will receive one of the two options below oral fluids

i) standard WHO ORS given for non-malnourished (experimental) versus
ii) WHO low-sodium rehydration solution called RESOMAL for children with severe acute malnutrition.

Which of the types of treatment a child is given will be decided by chance.

- All children will be closely watched to decide whether to make any changes to treatment. This monitoring will be through regular checks by the nurses. In this study, we will take an additional teaspoon of blood (5mls) on admission and a total of approximately a teaspoon (4.5mls) at 8 hours after admission from the veins of your child. In total we will take approximately a tablespoon (9.5mls) of blood during admission an extra drop (3mls) during the follow-up visits.

- As part of normal care the nursing staff place a soft tube called a catheter into the bladder in order to help us find out whether the fluids we are giving are having a good effect on urine output. From this we will take urine samples at 1hour, 4hours and 8 hours after admission without any additional discomfort to your child. This will be done by trained staff using clean equipment to minimize risk of infection.
- We may also look at other ways of how your child is responding to the fluids by using a small machine called an echo which is placed on the chest for 10-15 minutes to see how blood is pumped around the body. This will happen 5 times during the study (in hospital), the schedule will depend on the condition of the patient. We have used these before in lots of children – they will not hurt your child or will not involve any risk to your child.
- To be able to monitor your child's response to the fluids they will be given, we will possibly insert a tube through the nose into the stomach, a tube to collect urine (catheter)t and or fit him/her with diapers. These procedures will be done by well trained staff using clean equipment to minimize risk of infection.
- We will also ask you to come back to the hospital/clinic for follow up to check on your child's progress 7 days and 28 days after admission. This will also include measuring your child's weight and taking another measurement with the two machines again. At this follow up appointment we will take one further blood sample (a teaspoon of blood) and one more urine sample (this time the urine sample will involve passing urine into a container and will not involve insertion of a tube).

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

- Our priority for every participant is his or her well-being.
- Giving fluids by drips is extensively used in children in Kenya and other parts of the world. We will be monitoring your child very closely. If for any reason the doctor thinks that it is not in your child's best interest to be in the trial, then s/he will not be enrolled in the trial but will be given normal standard of care. There are no costs for being included in the trial.
- Taking blood from the arm causes a small amount of pain, , swelling, discomfort and minimal chance of infection. If this happens, we will provide treatment. The amount taken is too small to affect your child's health.
- Inserting a catheter involves a small amount of pain during the procedure, and a minimal chance of infection. If this happens we will provide treatment. Once the catheter is in place your child should not have any discomfort. The catheter will allow us to measure your child's urine output much more accurately.
- You will be asked to bring your child back for two follow up visits for routine health examination so we can find out how your child is doing. We will pay for your transport to hospital and back so you can attend these visits (depending on where you come from and the amount you spend on public transport). We will also compensate you for study related out of pocket expenses while attending this clinic visit at the rate of Ksh.350 per day for each follow-up visit. During the follow up visits, we will treat any illnesses we find your child has, or arrange referral to appropriate clinic or hospital if need be. These referrals will be done through the usual county government procedures using county government resources e.g. ambulance and nurse. We expect the follow up visits will take approximately an hour excluding travel time.
- An independent committee will monitor this research continuously to ensure participants safety and rights are respected at all times.

Are there any advantages to me/my child for taking part?

Your child will get close observation and our usual standard treatments during the trial, and by taking part your child may help us improve the care of children who have severe dehydration and Severe Acute Malnutrition in the future.

- 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 your child receives the normal treatment given to children who are not in the trial.

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. 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?

Individual names will be removed from all samples and replaced by codes, to ensure that samples can only be linked to the participants by people closely concerned with the research. All the research tests that will be done on the sample will be done here in Kilifi.

After the research, a small portion of the blood sample will be stored in our laboratories in Kenya. In future, new research may be done on these samples. Future research must first be approved by the national independent ethics committee to ensure participants' rights and safety are respected

Who will have access to information about 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 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.

In order to do this study, we will share anonymized individual and summary information we collect or generate with other collaborators involved in the study in ways that do not reveal individual participants' identities.

Who has approved this research?

All research at KEMRI must be approved before it begins by several national, local and international committees who look carefully at planned work. They must agree that the research is important, relevant to Kenya and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

What if I have any questions?

You are free to ask me or any of our staff any question about this research. If you have any further questions about the study, you are free to contact the research team using the contacts below:

Dr. Mainga Hamaluba KEMRI Wellcome Trust Research Programme, P.O. Box. 230, Kilifi. Telephone: 0748588041 or 0722 203417, 0733 522063, 041 7522063

If you want to ask someone independent anything 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 Head, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi; Telephone numbers: 0717 719477; 0776 399979 Email address: seru@kemri.org

KEMRI Wellcome Trust Research Programme consent form for:
Giving fluids to children admitted with Malnutrition and diarrhoea

I, [being a parent/guardian of _____ (name of child),] have had the research explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. And I agree to allow my child to take part in the research.

Please initial the sentences that reflect your choices, and then sign below:

_____ I do wish to be notified by investigators in the event of research findings of possible importance to my family members or myself. **Yes** □ **No** □

_____ I agree that the study team use the identifier that I have provided (telephone number, country ID number, etc.) to locate me in the future if need be. **Yes** □ **No** □

I agree to my child's samples being stored and used for future research **Yes** □ **No** □

I understand that I can change my mind at any stage, and it will not affect my child in any way.

Parent/guardian's signature: _____**Date** _____

Parent/guardian's name: _____ **Time** _____
(Please print name)

Where parent/guardian cannot read, ensure a witness* observes consent process and signs below:

I attest that the information concerning this research was accurately explained to and apparently understood by the parent/guardian and that informed consent was freely given by the parent/guardian.

Witness' signature: _____ **Date** _____

Witness' name: _____ **Time** _____
(Please print name)

Thumbprint of the parent/guideline as named above if they cannot write:

_____

I have followed the ethical procedure to obtain consent from the parent/guardian. S/he apparently understood the nature and the purpose of the study and consents to the participation of the child in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ Date _____

Designee/investigator's name: _____Time _____

(Please print name)

THE PARENT/GUARDIAN SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP