Wellcome Programme Patient Information Sheet and Consent Form for Clinical Trials

Impact of malaria prevention on health and education in Kenyan schoolchildren (revised 2010)

What is KEMRI?
KEMRI is a government organisation that carries out medical research. Research is different from normal treatment because research aims to find better ways of preventing and treating illness in the future for everybody's benefit. We are asking your permission for you/your child to participate in a research study.

What is this research about?
Malaria is a common problem in this area and may cause problems for the education and learning of children. The Government of Kenya is interested in understanding how malaria prevention and treatment can improve the education of schoolchildren when it is combined with effective teaching.

In this research, we aim to will test children to see if they have malaria parasites and then treating those found to be infected with a full course of anti-malarial drugs. We want to see if this process can make them healthier. The ways in which these drugs can make children healthier include removing the malaria parasite from their blood and improving the quality of their blood (by reducing anemia). We are also interested to see if the drugs can improve children's ability to concentrate in class and to improve their learning, particularly their ability to read. In this research we will also help support teachers to teach children to read well in class 1. In our study, schools will be selected by chance into four group: some schools will be tested and treated for malaria; some schools will have extra support for teachers of English and Swahili; some schools will be both tested for malaria and receive extra teacher support; and other schools will receive neither of the two programmes.

The decision on which schools receive the malaria testing and teacher support programmes will not be decided by the research team. It will be decided by a system based on chance. This means that your child(ren)'s school has an equal chance of being included in the two programes.

What will it involve for my child(ren)?
We will take a small sample of blood from your child(ren) to find out if they have malaria parasites and to determine their haemoglobin level. Haemoglobin gives blood its red colour and carries oxygen around the body. If there is not enough haemoglobin a child can become easily tired – this is called anaemia. We will use a sterile needle to make a prick on a finger and collect one drop of blood and measure the amount of haemoglobin in a machine. This sample will be less than half a tsp (2ml) and will be taken from your child(ren)'s finger. These samples will be used to prepare slides which will be examined under a microscope. In addition, we will ask your child(ren) to participate in a number of tests of educational performance. These will measure how well you child concentrates and their progress in learning to read and learning mathematics. At the end of the study, we will ask your child for a stool and urine sample which will be examined for intestinal worms and schistosomiasis.

In the schools allocated to the malaria testing group, all children in classes 1 and 5 will be testing using a rapid diagnostic tests and those children found to have malaria parasites will receive artemisinin-based combination therapy (ACT) according to national guidelines. Treatment will be given at school for three days. In the schools allocated to the other groups, there will be no testing for malaria. The allocation of school to different groups will be determined by a lottery. The chance of being placed into each of the study groups is the same. You will be informed which group your child's school has been allocated to.

Certain schools, which may or may not include your child(ren)'s school, will also receive an education intervention at the start of the study. Which schools receive this intervention will also be randomly allocated. However, all schools will receive the education intervention at the end of the study.

Altogether we expect the trial to make two visits to your child(ren)'s schools each year, and the study will last two years. This will include taking another small sample of blood of less than half a teaspoon of blood (2ml) from your child(ren)'s finger to check for malaria parasites and haemoglobin. We will check your child for three days after treatment to assess progress and for any side-effects from the ant-malarial treatment. Later in the study we would also like to ask you some questions about your children and their education.

How long will this take?
The tests of reading, mathematics, attention and concentration will take one hour per day for three school days. The measurements and medical tests should take only 15 minutes and we will write the results on a piece of paper for you to have. The questions we ask you about your children will take about an hour of your time.

Are there any risks or disadvantages to me/my child of taking part?
Which group your child is given will be determined by chance. The group your child has been allocated to may prove to be less effective than the other groups. This will not be known until after the study is completed.

The drugs used are known to be safe in most people, and are now in common use in Kenya. Artemisinin-based combination therapy (ACTs), such as Coartemm, has no serious adverse events for children. If treated, your child will be monitored closely afterwards for any possible side effects of the drugs and will receive appropriate medical care for any such problem during the course of the study.

The finger prick blood sample may cause minor temporary discomfort for children. The amount of blood removed will be too small to affect your child's health. The information generated will also be very useful for making decisions about malaria control in your child(ren)'s school and our country as a whole.

If for any reason the doctors or nurses monitoring the trial think your child(ren) would benefit from leaving this trial, they will recommend this to you and ensure that you receive the normal standard of treatment for people who are not in the trial.

Are there any benefits to me/my child of taking part?
The benefits for your(ren) child taking part are that they get malaria treatment during the trial. The knowledge gained from this study will help the country of Kenya in determining the best way to treat and prevent malaria in schoolchildren.

What will happen if I don't agree to participate?
All participation in research is voluntary. You are free to decide if you want your child(ren) to take part or not. Your child(ren) will still receive the recommended standard of care for worms 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 their care now or in the future.

What happens to the samples?
All of the tests that are needed as part of this research will be done locally in Kenya.

Who will have access to information about me/my child in this research
We will take strict precautions to safeguard your child's personal information throughout the study. 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.

Who has allowed this research to take place?
All research at KEMRI is approved by national independent expert committees in Nairobi and a committee in Kilifi to make sure the research is conducted properly and that participants' safety and rights are respected.

What if I have any questions?
You may ask any of our staff questions at any time. You can also contact those who are responsible for the care of your child and this research:

Dr. Simon Brooker, at KEMRI – Wellcome Trust, P.O. Box 43640 - 00100, Nairobi, Kenya
Tel: +254 20 2715160 or 2720163 or 2719936, Mobile: +254 724 350 056

If you have questions about your rights as a study participant, concerns about the research or if you want to ask someone independent anything about this research please contact

Community liaison officer, at KEMRI – Wellcome Trust
P.O.Box 230, Kilifi. Telephone: 041 522 063

Or

Chair, KEMRI/National Ethics Review Committee
P. O. BOX 54840-00200, Nairobi, Telephone: 020 272 2541

This research is supported by the KEMRI and the London School of Hygiene and Tropical Medicine who will pay for any treatment or compensation in the unlikely event of any injury resulting from this trial.