**Patient Information Sheet**

**(This form will be translated to Solomon Islands PIgin):**

This is for you to keep.

**A comparison of two artemisinin combination therapies (ACTs) in combination with primaquine for radical cure of *Plasmodium vivax* malaria in the Solomon Islands: the “ACT-radical” study.**

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You (or your child) have been diagnosed with a type of malaria (called “vivax malaria”). We would like to invite you to participate in a research project that aims to work out the best way of treating this type of malaria.

The parasite that causes vivax malaria can infect not only your blood but also your liver. The usual malaria medicines only kill parasites in blood but usually make people feel much better very quickly. Unfortunately these usual medicines do not kill parasites that “sleep” in the liver. These parasites can “wake up” later on (usually in one or two months time), go into the blood, cause sickness again and be passed on to other people in your community by mosquitoes. This can happen a number of times and such episodes are called “relapses”.

Unlike the usual malaria medicines, a special, different kind of malaria medicine, called primaquine, *can* kill sleeping liver parasites. So to kill all the parasites in the body and prevent future relapses we need to use two medicines, one for the parasites in the blood and one for the parasites in the liver.

Unfortunately, whenever we combine medicines like this, it is possible that one medicine might interfere with the other. There are many different medicines for killing blood parasites but we don’t know which of these will work best in combination with the drug for killing liver parasites. We are worried that the usual blood parasite-killing drug used in the Solomon Islands (called “Co-artem™”) might interfere with the liver-parasite killing medicine (primaquine). We therefore want to see if a different type of blood parasite-killing medicine (called “Eurartesim™”) might be a better medicine to combine with primaquine.

To work out the best way to treat this type of malaria, we are conducting a research study that will compare how effective different drug combinations are for killing liver parasites. We will do this by comparing three different treatments:

1. Giving primaquine (for killing liver parasites) together with the usual treatment for killing blood parasites (“Coartem” for 3 days).
2. Giving primaquine (for killing liver parasites) together with a different type of treatment for killing blood parasites (“Eurartesim™” for 3 days).
3. Giving only the treatment for killing blood parasites (“Coartem™” for 3 days) without any primaquine. **This is usually how most people would currently be treated in the Solomon Islands.** However as well as this, we would also give primaquine in six months time to kill liver parasites.

We will then compare how well the three different treatments work, by watching closely for any malaria relapse over the next 6 months. Which of the three treatments you receive is determined randomly (by chance – like tossing a coin) and will be chosen by a card drawn from a sealed envelope. None of the researchers will know what this is until the envelope is opened and neither you nor the research team will be able to choose which of the three treatments you receive. It is important that before you agree to participate, you understand that you cannot choose which of the three treatments you receive.

The study is being conducted in the Tetere area of the Solomon Islands and will aim to have 380 people participate. We have already conducted meetings with community leaders here to inform them of this study.

**What are the potential risks if I decide to participate?**

1. We will need to obtain regular small blood samples at the start and then either once a week, once every fortnight or once a month (15 times altogether) for the full 6-month duration of the study. We do this by pricking the finger with a small needle and then squeezing out a few drops of blood. This is the usual way we test for malaria and only causes minor discomfort or a small amount of pain. It can be mildly distressing to very small children and can leave tiny bruises on the finger tips.
2. We will also take a larger sample of blood (about one teaspoon full) with a needle from the vein at the start of the study (today) and then again in 7 days time. For adults and children over the age of 5, we will also take 2 more blood tests like this (a teaspoon full of blood taken through a needle in the vein) in 3 days time, one more in 7 days time and two more in 14 days time (total of 7 blood samples through the vein over a 14 day period). Taking blood through a needle in the vein can be slightly painful and lead to bruising.
3. The study will require that we see you up to 15 times over the next 6 months. This time commitment could be inconvenient for you but we will aim to arrange meetings by visiting you at your home, school or workplace wherever possible to minimize this inconvenience.
4. As with any medicines, side effects can occur, though we believe the chance of serious side effects are low. The medicines used for treating parasites in the blood (Coartem™ and Eurartesim™) are generally very safe and have been given to millions of people around the world without major problems. If you were not participating in this study, you would usually be treated with Coartem™ anyway. However if you were not participating in this study, you would probably not ordinarily receive the medicine for killing liver parasites, primaquine. So it is important that you understand the side effects that can occur with this medicine. They can include:
5. Abdominal pain, vomiting or nausea. These usually occur when this medicine is taken on an empty stomach. We will ensure you have your medicine with food which should prevent these side-effects.
6. Destruction of blood cells – called “haemolytic anaemia” (not enough blood) and leading to jaundice (yellow eyes and skin). This only happens in some people and we have performed a test beforehand to see if you are at risk of this side effect. If we are asking you to participate it means that your test was negative, suggesting you are not at high risk of this side-effect.
7. Changes in the ability of the blood to carry oxygen, resulting in lips and tongue turning blue and feeling short of breath. This is rarely severe but we will monitor for it carefully with a special machine and stop treatment should it become a problem.

**What tests will be conducted on my blood samples?**

Blood samples taken from you as part of this project will be used to test for malaria parasites in the blood, to check for side-effects (such as a low blood level), and to measure how much of the malaria medicines is in your bloodstream at various times.

We will also use blood taken from you to analyse your genes (DNA) because this can be important in determining how well these malaria drugs work and whether they cause side-effects. This is a very important part of the study and it is important you agree to having your genes tested in this way before coming into this study.

**What about my privacy and confidentiality?**

We will need to take your name, place of residence and phone number during the study so that we can contact you to check on your progress and arrange follow up. However once you have completed the study, we will not keep these details nor any other information that could identify you personally. Any details about you and your health will therefore be kept strictly private and confidential and not be available to anyone else other than the study investigators. No details about you or your own individual health will be published or presented in any public forum.

**What are the potential benefits to me if I decide to participate?**

We believe you may benefit from the very careful monitoring for side effects that we will perform. This would not usually occur if you had standard treatment. It is also possible that by participating in this trial there is a lower chance of you having a relapse from vivax malaria in the next few months. These relapses can sometimes be unpleasant and can contribute to other health problems like anaemia (deficiency of blood).

**What will I have to do if I agree to participate?**

Firstly, the researcher will ask you some questions, do a brief examination and take a blood sample through the vein. You will be given a standard 3-day course of malaria treatment (to kill blood parasites) and you may or may not also have a 14-day course of primaquine (depending on directions received after opening the envelope). You will need to have another blood test taken through the vein in 7 days time. You will need to take your prescribed medicine each day and have a brief check-up and finger-prick blood test 1, 2, 3, 7, 10, 14 and 28 days from now. You will then need to be seen every two weeks for the next 2 months and then every month for 3 months after that. At each visit you will have a sample of blood taken by finger-prick to check for relapse of parasites in your blood.

If you are an adult or a child over the age of 5, we will also arrange to take two more blood tests through the vein in 3 days time, one more in 7 days and 2 more in 14 days time.

**What will happen if I decide not to participate?**

You will receive usual treatment through the clinic according to the usual national treatment guidelines. You will not be penalised or discriminated against and your usual medical care will not be influenced in any way by your decision not to participate. It is important to remember that this decision is yours and yours alone.

**What if I decide to participate but then later decide I no longer want to continue in the study?**

You are free to withdraw from the study at any time for whatever reason you like. Again, you will not be penalised or discriminated against and your usual medical care will not be influenced in any way by your decision not to participate.

**Who should I contact if I have any concerns about the study or wish to find out more?**

If you have any concerns or complaints you can arrange to contact the Solomon Islands Human Research Ethics Review Board:

Ms Freda Pitanka, SIHRERB Secretary,

Ministry of Health & Medical Service, P O Box 349, Honiara

Phone 23207 Fax 20085

Email: [freda.pitakaka@moh.gov.sb](mailto:freda.pitakaka@moh.gov.sb)

Or

Mr Crhis Becha, SIHRERB Chairman, Undersecretary Health Improvement

Ministry of Health & Medical Services, P O Box 349, Honiara

Phone 23682

Email: [cbecha@moh.gov.sb](mailto:cbecha@moh.gov.sb)

You can also talk to any of the research staff / study clinicians or, should you wish, you can contact one of the following senior investigators:

**In the Solomon Islands:**

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