UCLouvain
Institut de recherche expérimentale et clinique

Pôle de recherche EPID
Epidémiologie et biostatistique

Responsable de Pôle : Prof Annie R ROBERT

ARTEMISA TRIAL FOR COHORT SCREENING AND TEAS_V1

INFORMED CONSENT FORM FOR STUDY PARTICIPANTS

This Informed Consent Form is for men and women who work or study in the University of Buea and the University of Rwanda, who we are inviting to participate in research to contribute to the elimination of Plasmodium carriers in high malaria transmission settings with *Artemisia afra* tea infusions. The title of our research project is " Activity level, optimal dosage, safety, and accepted formulation of *Artemisia afra* tea infusions in eliminating plasmodium reservoirs in malaria endemic areas of Cameroon and Rwanda."

***Name of Principal Investigator*:** Abenwie Suh Nchang

***Name of Organization* :** Université catholique de Louvain, Belgium; Université Libre de Bruxelles, Belgium ; University of Buea, Cameroon; Université de Liège, Belgium

Name of Sponsors :

Pr Annie Robert, Université catholique de Louvain
Pr Jacob Souopgui, Université Libre de Bruxelles
Pr Stephen Ghogomu, University of Buea
Pr Michel Frederich, Université de Liège
Pr Jean-Claude Twizere, Université de Liège

Name of Proposal and version: Artemisa trial_v1_15.11.2021

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form.

PART I: Information Sheet

Introduction

I am Abenwie Suh Nchang, working for the IREC-EPID Research unit in the Public Health school of the UCLouvain- Belgium. We are doing research on Malaria disease, which is very common in this country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information, and I will take time to explain. If you have questions later, you can ask them of me, the study doctor, or the staff.

Purpose of the research

Malaria is one of the most common and dangerous diseases in this region (African region) and everyone is exposed to the risk of malaria transmission. The medications and methods that are currently used to

help people with malaria are not as good as we would like them to be. In fact, there are some people who when given the malaria medication ACT (Artemisinin combined therapies) are not completely cured. There are other people who have malaria but do not have signs of malaria like fever; they are called carriers because if a female mosquito bite them and aspirate their blood, the mosquito will help in spreading the infection to other people. There is a new medication which may work better in treating all these people. In fact, some people in our region are already drinking this medication to treat malaria. The reason we are doing this research is to find out how the new medication Atremisia afra works in treating malaria in people who have malaria in their blood but do not have fever, and what quantity these people should take to be completely cured.

Type of Research Intervention

This research will involve testing people who are not sick to find out if they have malaria. A malaria rapid diagnostic test (mRDT) will be done and the RDT shows malaria parasite in the blood, another test called qPCR, will be done for confirmation. Those that the qPCR test show malaria in their blood will be prescribed the new medication, *Artemisia afra* tea infusions, to drink for a maximum period of 4 weeks. During the time that they are taking the treatment, their blood will be tested every week to see how the medication is treating the malaria. So, they will be expected to come for follow-up visits to the study site (clinic) every week for 4 weeks after the first visit.

Participant selection

We are inviting all adult students and workers in the University of Buea and the University of Rwanda, who are at least 18 years old to participate in the research on the new malaria medication.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at your University will continue and nothing will change. You may change your mind later and stop participating even if you agreed earlier.

Information on the Trial Medication, *Artemisia afra*

The medication we are testing in this research is called *Artemisia afra*. It has been used by some people before, to prevent malaria that shows fever and who live in areas where malaria is common. We now want to test the medication on people who have malaria but do not have fever. This second research is called a "phase 2" trial. The Artemisia afra tea infusions will be prepared (drying, weighing, and packaging of leaves in tea bags) in the pharmacology unit of the University of Liege in Belgium. We do not expect any side effects or know of any problem or risks of this medication since some people in this community have been drinking it with no problem.

Some participants in the research will not be given this tea which we are testing. Instead, they will be given flavoured tea. There is no risk associated with the flavoured tea and no known problem, but it does not have the *Artemisia afra* tea content.

Procedures and Protocol

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

A. Unfamiliar Procedures

Randomisation: Because we do not know the best effective quantity, mixture, and taste of the new malaria medication, we need to compare different quantities, mixtures, and tastes. To do this, we will put people taking part in this research into 8 groups. The groups are selected by chance, as if by tossing a coin.

Participants in 6 groups will be given the test medication while participants in 2 groups will be given the medication that does not contain the test substance called placebo.

A placebo is an inactive medicine that looks like real medicine, but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. Sometimes when we want to know whether a new medicine is good, we give some people the new medicine and some people the pretend or dummy medicine. For the research to be good, it is important that you do not know whether you have been given the real medicine or the pretend or dummy medicine. This is one of the best ways we have for knowing what the medicine we are testing really does.

It is important that neither you nor we know which of the medications you are given. This information will be coded using code that can only be understood by the principal investigator, it is accessible only to him/her. This is the best way we have for testing without being influenced by what we think, or hope might happen. We will then compare which of the two has the best results.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the medication is doing, we will find out which medication you are getting and make changes. If there is anything you are concerned about or that is bothering you about the research, please talk to me or one of the other researchers.

If someone develops malaria symptoms (like fever) along the line, and we find that the new medication that is being used does not have the desired effect, or not to the extent that we wish it to have, we will use what is called a “rescue medicine”, The medicine that we will use is called ACT and it has been proven to treat malaria that has fever.

For the blood test, we will take blood from your arm using a syringe and needle. Each time we will take about 1ml of this much blood (show a spoon, vial, or other small container with a small amount of water in it). In total, we will take about 5mls of this much blood in 5 weeks (show the quantity). At the end of the research, in 1 year, any leftover blood sample will be destroyed.

B. Description of the Process

During the research, you will make five visits to the clinic.

- At the first visit, a small amount of blood, equal to about a teaspoon, will be taken from your arm with a syringe. This blood will be tested for the presence of the parasites that cause malaria infections. We will also ask you a few questions about your general health and measure how tall you are, how much you weigh, and verify your hospital records. If you have malaria, then you will be given either the tested medication or the placebo. As explained before, neither you nor we will know whether you have received the tested or the dummy/pretend medication.

- At the next visit, which will be one weeks later (Day 7), you will again be asked some questions about your health and then your blood will be taken again and tested to see how the medication has worked to kill the parasites and how many parasites are left.
- After one week (Day 14), you will come back to the clinic for a blood test to see how the medication has worked to kill the parasites and how many parasites are left and you will again be asked some questions about your health.
- After 2 weeks (Day 28), you will come back to the clinic for another blood test to see how the medication has worked to kill the parasites and how many parasites are left you will again be asked some questions about your health.
- After the 2weeks visit, you will do a last visit 1week later (Day 35), and a final blood test will be done, and conclusions will be made on how the medication works to kill malaria parasites in a person who does not have fever.

Duration

The research will take place over 35days in total. During that period, it will be necessary for you to come back to the clinic four times, for about 1hour each day. We would like to meet with you, one week after your last clinic visit for a final check-up.

In total, you will be asked to come 5 times to the clinic in 5 weeks. At the end of 5 weeks, the research will be finished.

Side Effects

As already mentioned, we do not expect any side effects or know of any problem or risks of this medication (*Artemisia afra* tea) since some people in this community have been drinking it with no problems.

Risks

By participating in this you will not be at greater risk than you would otherwise be, but if something unexpected happens, we will provide you with the possible intervention to resolve the event.

Benefits

If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. There may not be any benefit for you, but your participation is likely to help us to know if the medication actually decreases malaria parasite in the blood of carriers. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

Reimbursements

We will reimburse the transportation cost during visit days and a health insurance will be contracted for participants during 6months. You will not be given any other money or gifts to take part in this research.

Confidentiality

With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one, but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is, and we will lock that information up with a lock and key.

It will not be shared with or given to anyone except the main people involved in the research who are, the research sponsors, the principal investigator, the Data and Safety Monitoring Board (DSMB), and your clinician.

Sharing the Results

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the University community, and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and refusing or stopping to participate will not affect your rights or benefits in your University institution.

Who to Contact

If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following addresses: Abenwie SN, Tel (+237) 676786985, Email: abenwie.suhnchang@uclouvain.be

This proposal for this research has been reviewed and approved by the Faculty of health science IRB, University of Buea, and the Rwandan National ethics committee, which is a committee whose task it is to make sure that research participants are protected from harm.

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked, have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. They will participate in a clinical trial of *Artemesia afra* treatment
2. They will make visit the study site a total of five times and their blood will be collected and tested all these times
3. If they choose not to participate in the study or stop participation at anytime it will not affect the services or benefits, they have in the university.
4. They will be randomized into different treatment groups by random allocation and neither them nor the health professional will know to which group they are allocated.
5. They will receive either the test medication or the placebo but those who receive the placebo will be given a sure treatment for malaria after the 28^{th} day of the study.
6. They will not be paid to participate in the research, but they will be reimbursed their transportation cost during visit days and benefit health insurance for 6months.
7. The blood samples collected will be destroyed one year after the study is done.
8. The information provided in the study will be kept confidential and only the key people involved in the research shall have access to it.
9. They will benefit from free medical care during the study period, and they will not pay for the test treatment they will receive.
10. We do not expect them to have any problems after taking the treatment but if any problem occurs, we will provide the possible intervention to resolve it.
11. The results of the research will be communicated to the university community first, and then to the wider community for others to learn from the research. The results will not carry individual information.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year