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Information sheet

Principal investigator: Dr Gustave Simo

Title: "TrypanoGEN^{+}: the genetic determinants for schistosomiasis".

Introduction

I am Dr Gustave SIMO, researcher and lecturer at the University of Dschang. We would like to invite you and your children to participate in a study that aims to identify families whose children carry a high load of worms or schistosomes in order to understand the hereditary basis of this susceptibility to heavy schistosome burden. Your participation and that of your children is entirely voluntary. Before agreeing that your children will take part at this study, we request you to read this form, or we go through it with you. This form is called the inform consent form. It describes the objective of the study, the risks, benefit and your alternatives to participle and to enable the participation of your children. The reasons and impact of this study will be explained to you as contained in this inform sheet. If you don't have enough time, a copy of this inform consent sheet will be handed to you in order to enable you to understand more about the subject and its importance. Thereafter, you will be invited to give your accordance for your participation and that of your children if you wish. You are not obliged to take an immediate decision concerning the involvement of your children. You are free to receive advice from another person of your choice before making a decision. If you do not fully understand the purpose and outline of the study, you are free to consult me at any time for deep explanation.

Schistosomiases are diseases caused by worms. They are a major health problem in several countries and more than 240 million people are infected with nearly 85% in sub-Saharan Africa. About 200,000 people die each year because of this disease. Your village is one of those whose children suffer from these diseases. If infested children are not treated, these diseases will cause abdominal pain, dysentery with stool containing blood. These diseases can sometimes lead to other digestive disorders such as loss of appetite, vomiting and nausea. Examination of your stool, urine or blood and those of your children using modern techniques will identify infested persons, especially those who are heavily infested and who spread, maintain and transmit the disease. Their management will prevent the occurrence of adverse effects while limiting the transmission of the disease. Your village was selected as a model for this project. Conventional methods will be used to analyze stool and urine in order to identify infested persons and provide them free treatments.

Objective of the study: This project aims to identify the human genetic determinants that predispose to high loads of *Schistosoma mansoni* in order to better understand the transmission of intestinal schistosomiasis.

Population and study period

The study population will be performed on children in school and out of school of less than 15 years old and living in villages or areas at risk for schistosomiasis. Parents, brothers and sisters of children showing high schistosomes' burden will also be included in this study. This three-year study will run from November 1, 2018 to November 31, 2021.

Protocol

All children of households and schools will be admitted to this study. A questionnaire form containing information on the understanding of the study and risk factors related to the disease will

be given to the guardian or parent of each child. To fill this form, parents or guardians will be assisted if necessary by a member of our team for any questions of misunderstanding. Children will be asked to ease his/her self in a stool box and to provide urine. If the children have relieved themselves before our arrival, and it is impossible to ease again, sterile boxes for stool and urine samples will be given to the parents. In each of these boxes, urine or stool sample will be introduced early in the morning after waking. In the school setting, the inform sheet and informed consent will be sent to parents or guardians two days before the collection date. For children whose parents or guardians have consented, stool and urine samples will be collected and put into boxes that will be delivered to us the next morning day in school. One part of stool and urine samples will be analyzed in the nearest health facility by simple and fast techniques to investigate the presence of schistosomes and intestinal worms. Free treatment will be given to all infested individuals.

The remaining stool and urine samples will be sent to the laboratory and then kept in freezers for more accurate analyzes to identify children with high loads of schistosomes. All children with high schistosome burden will be identified and selected for further study. The families to which these children belong will also be identified and included in this study. Once families are selected, a second mission will be made to these families in order to ask for the consent and participation of family members. For family members who have agree to participate in the study by signing the informed consent form, a questionnaire form will be administered and stool and urine samples will be collected and examined for schistosomes and other intestinal worms. People with schistosomes or other intestinal worms will be treated free of charge. About 5 ml of blood or 2 ml of saliva will be collected from family members who agree to participate in the study. These blood or saliva samples will be used for DNA extraction.

Biological samples that you will provide

If you decide to participate at this study, a nurse or doctor will examine you. Following this examination, you will provide stool, urine, blood or saliva samples. They will be tested for schistosomes and other intestinal worms.

Storage of samples

Your samples will be stored in secure freezers at the University of Dschang for 5 years or more, depending on your permission. No personal information will be linked to the samples and no one will know if they belong to you, with the exception of the research team. If you do not want your samples to be used for future research, you can let us know at any time and we will remove them from the storage.

Outcome of samples

For other research projects that are not part of this study, the parent or guardian of each child will be contacted again for a second approval of the use of the samples. At the end of the study, the remaining samples will be removed from boxes and preservation tubes and discarded. The boxes and tubes will be soaked in a disinfectant solution before being thrown away.

Voluntary participation of your children

You are invited to this study because your participation will be useful to the extent that your samples will allow us to identify people with high worm burden in order to understand the reasons that predispose them to these strong parasitaemia. Your participation is entirely voluntary and you have the right to refuse and/or involve your children without any prejudice. If you agree, you are free to be withdrawn and to withdraw your consent at any time; without giving any reason and without reprisals for you and your children. You also have the right to refuse to answer certain questions without any consequences. The refusal will not affect your access and that of your children to medical care. Your children and you will have the same treatment as those who

participate. Denying participating, interrupting your participation or withdrawing your consent will not affect your rights to benefit from mass treatment campaigns carried out in your village.

Ethical consideration

Potential risks/discomfort

The ethical issues related to the implementation of this study are the violation of participants' autonomy and psychological damage. There may be contamination of the parent during the sampling or small pains during blood collection. To limit the risks, we will insist as much as it is necessary to collect the stools ourselves. Blood samples will be taken aseptically by the medical staff of the health facility located near the study site to minimize the risks and pains. This staff will receive financial compensation on the basis of their experience and following the Cameroonian regulations. After the medication, your child may feel stomach pain; it will be temporary.

Potential benefits

Participating in this program, you would have an idea of your parasitic status with respect to infections caused by schistosomes and other intestinal worms as well as information on the behavioral habits that can lead to these infestations. You would also have the parasitic status of your children. In the case of a positive test, the treatment will be free for schistosomiasis and other intestinal worms identified. This benefit concerns directly you and your children. It concerns your family, your village, your country and all the people of Africa. For your participations, people with high loads of schistosomes will be identified and the hereditary bases that support the susceptibility to these high parasite loads will be identified for a better management of this disease.

Confidentiality and respect of participants' live

The information collected will be kept confidentially within the limits allowed by the law. The collected data will be processed and stored in a secure database and a confidential code will identify the samples collected. Only investigators will have access to the code. The name and code assigned to each individual will be secure and will not be released except to the doctor in charge of treatment if necessary. The information will be stored in such a way that the name cannot be known.

Incentive/compensation

No incentive or remuneration will be paid for your participation. However, other intestinal worms will be investigated and those infested by these worms will be treated freely of charge. There will be no reward for participating in the study. Your children will not receive money from us or any other person as a result of using the samples they have provided. It is unlikely that you and your children will be physically harmed by any of our sample collection procedures. If this happens, the affected person will be treated and financially compensated according to local law and in accordance with the insurance policy in force. You agree to give free of charge the property rights that your children and you may have to the samples and medical, scientific or commercial products such as drugs, diagnostic or other inventions arising from the use of specimens. Your participation is therefore free and is done in a spirit of helping future generations to fight against schistosomiasis

Sharing data and results

The collected samples will be processed and sent to researchers in other countries who have the appropriate machines for further analysis. We will take the genetic material of blood or saliva to read (almost as if reading a book) and create information about hereditary traits that are specific only to you and your children. We will use this information in combination with other information that was collected from you and your children. It is now common that genetic information can be shared with researchers around the world. The advantage is that many researchers can use the same information for different research projects. We would also like to share your genetic information and some clinical information with other researchers for other projects. If

you and your children participate in this study, you will also need to agree to share your genetic information for further research in the future.

Results will be published in journals and presented during seminars. A full report will be prepared. Results will be given to you during meeting involving participants and local leaders.

Right to refuse or abandon the study

You are not obliged to participate and involve your children in this program. If you do not want, nothing will change on the treatment to be given to you against this disease. You can stop your participation at any time if you wish without losing your rights. Your treatment and those of your children will not be affected if you stop your participations.

Problems or questions: Who to contact?

This program has been submitted and approved by the Ministry of Health through the National Ethics Committee for research on human health (CNERSH). This committee is in charge of protecting people who participate in this research program. If you have questions now or after, you can contact the doctor of your hospital or Dr Gustave SIMO at the address indicated below:

- Dr SIMO Gustave
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Adresse du Comité National d'Ethique de la Recherche pour la Santé Humaine (CNERSH)

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