Lamp4yaws: Participant information sheet

Project PI: Michael Marks, London School of Hygiene and Tropical Medicine

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and to talk to others about the study, if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Why are we completing this study?

Yaws is a highly contagious infection and people can get it through direct contact with infected individuals. The condition starts with an ulcer on the skin. If left untreated, the ulcer can develop into deformities on the bone that can last forever. There is a global effort to eliminate yaws from communities by 2030. Sometimes it is not easy to tell if a person has yaws as there are many different germs/bacteria that cause skin ulcers. A new test has been made to see if a person has yaws. We want to know if this test is good enough to detect yaws, and for this, we need to collect samples of people with skin ulcers. We will be recruiting participants in three countries: Cameroon, Cote D'Ivoire and Ghana between 2020-2022.

Why have I been chosen?

Today, we are in your village because yaws occurs here. Our aim is to find 200 people with ulcers and positive blood tests in each country.

What will taking part involve?

We will perform a quick skin examination of the arms, legs and torso to see if you have any signs of yaws on your body and we may perform a finger prick to collect up to six drops of blood from you. If you do have signs of yaws we will also use your blood sample to test to see if you have yaws in your blood. If this test is positive we will also collect some cotton swabs by rubbing the lesion. If you have lesions we will offer you azithromycin antibiotic or refer you to services for free treatment. This drug is safe and is used to treat many other of illnesses. The samples you provide will be tested for yaws within the country. We may send some of your samples to our European partners to improve the test and find out what other germs may be causing lesions or may be common in your community.

After taking your sample, we will come back within 4 weeks to check whether the skin lesion has healed up or not. If the lesion has not healed we may collect more swabs and we will offer you a different drug to treat the lesion.

Do I have to take part?

It is entirely up to you to decide to join the study. We will describe the study and go through the information sheet. If you agree for you or your dependent to take part, we will then ask you to sign a consent form. You or your dependent is free to withdraw at any time, without giving a reason. Even if you refuse to take part in the study we will refer you for free treatment for your ulcer.

What are the possible disadvantages and risks of taking part?

There are very few risks to taking part in this survey. The finger pricks and the ulcer swab can be uncomfortable. We have used these procedures in many surveys and no serious risks have emerged.

What are the possible benefits of taking part
If you are found to have ulcers we will offer a free treatment, or refer you to services for free treatment. This treatment should get rid of these ulcers. The information we get will help improve the diagnosis of people with yaws in all around the world.

What happens when the research study stops?
After the research study stops, the findings of the survey will be published in an easily accessible format. We may store the blood (up to 6 drops) and swabs indefinitely in case anyone should question our results. We may also anonymously test those samples in other related studies.

Photographs may be used for teaching and research purposes, and may be published in open access format meaning they may become available on the internet. However, if photographs are published, we would ensure that the photographs would not be linkable to you as an individual.

Will my taking part in the study be kept confidential?
Yes. All information collected about you or your dependent during the course of the research will be kept strictly confidential.

If you or your dependent joins the study, some parts of your medical records and the data collected for the study may be looked at by authorised persons from the London School of Hygiene & Tropical Medicine. They may also be looked at by representatives of regulatory authorities and by authorised people from the Ministry of Health to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research site.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time. If you withdraw from the study, we will destroy all identifiable samples, but we will need to use the data collected up to your withdrawal.

What will happen to the results of the research study?
The results of the study will be published, and shared with healthcare bodies in Ghana, Cote d'Ivoire and Cameroon and the wider international community for the purposes of making policy decisions with the Ministry of Health.

Who is organising and funding the research?
The European and Developing Countries Clinical Trials partnership are paying for the study. The study is being designed and coordinated by, the London School of Hygiene & Tropical Medicine.

Who has reviewed the study?
This study was given a favourable ethical opinion by the London School of Hygiene & Tropical Medicine Research Ethics Committee and the National Health and Research Ethics Committee (Reference: 21633)

Contact Details
Should you have any questions or worries about the project, please feel free to contact any one of the study investigators:
Rebecca Handley (Study coordinator) Rebecca.handley1@lshtm.ac.uk +44207 927 2866

Michael Marks (Principle investigator) Michael.marks@lshtm.ac.uk +44207 927 2457

CONSENT SIGNATURE FORM

Stick ID barcode label here

Title of Research:

Loop mediated isothermal amplification test development, implementation and evaluation for yaws eradication

Statement

☐ I have read the information on this study/research or have had it translated into a language I understand. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.

☐ I understand that my (my child's) participation is voluntary. I understand I may withdraw from the study at any time without giving a reason and that this will not affect my (my child's) normal care.

☐ I understand that the information or tissue sample collected about/from me(my child) will be stored indefinitely and may be used to support other research in the future, and may be shared anonymously with other researchers, for their ethically-approved projects.

☐ I give consent for lesion photographs taken of me or my child to be taken and used for the purposes of this study, which may involve dissemination to relevant external parties and potential publication online. These will not show any identifiable features.

☐ I know enough about the above named study and agree to take part.

To check appropriate one:

☐ *(A) Participant:*

NAME OF PARTICIPANT_____

SIGNATURE/THUMB PRINT OF PARTICIPANT: _____

☐ (B) *If participant is under the age of consent)*

GUARDIAN'S NAME:_____

GUARDIAN'SSIGNATURE/*THUMBPRINT*:_____

RELATIONSHIP TO THE CHILD: FATHER [ ] MOTHER [ ] OTHER [ ]

Translator (if applicable): I have read this form and the information sheet to the above person and am sure that he/she has understood what is required of someone enrolling in this study and that they agree to enrol in the study.

Signed:…… Date:

Participant information sheet
Lamp4yaws – Social Science studies

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and to talk to others about the study, if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Why are we completing this study?
Yaws is a highly contagious infection and people can get it through direct contact with infected individuals. The condition starts with an ulcer on the skin. If left untreated, the ulcer can develop into deformities on the bone that can last forever. There is a global effort to eliminate yaws from communities by 2030. We are currently conducting a large study to assess the reliability of a new diagnostic test, alongside this we also want to learn more about peoples understanding of yaws and other skin conditions. We also want to find out if and where people may seek treatments and opinions about yaws diagnostics tests and treatments.

Why have I been chosen?
You have been chosen because you live in a yaws endemic community, or you are a healthcare worker, laboratory scientist of key stakeholder that may be involved in yaws control programs or yaws surveillance.

What will taking part involve?
We are inviting you (or your dependent) to take part in either focus groups discussions or small group/individual interviews about yaws. If you take part these sessions will be recorded with a digital recorder. We estimate that each interview/focus group discussion will last around 60-90 minutes to complete. In the interview/focus group discussion we will ask you (or your dependent) about your (their) experience with yaws in the community. We will also ask you (or your dependent) about your (their) personal experiences relating to care and treatment of yaws and other skin diseases.

Do I have to take part?
It is entirely up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree for you or your dependent to take part, we will then ask you to sign a consent form. You or your dependent are free to withdraw at any time, without giving a reason.

What are the possible disadvantages and risks of taking part?
There are very few risks to taking part in this survey. We will be asking you (your dependant) questions about your (their) daily experience. You (they) don't have to answer questions you (they) don't want to answer. If you feel the need to talk or confide in someone after the group discussion, we can refer you to the appropriate services.

What are the possible benefits of taking part?
There are no direct benefits to you taking part in this study but the information we get will help improve the diagnosis of people with yaws in all around the world.

Will my taking part in the study be kept confidential?

Yes. All information collected about you or your dependent during the course of the research will be kept strictly confidential. All researchers will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research site. Your name will not be linked to any reports or articles. The data from this interview will remain confidential and protected. After the interview, we will transfer the information to a password-protected computer and destroy the contents of the recording device.

What will happen if I don't want to carry on with the study?

You can decide whether or not to participate in the group discussion and you are free to withdraw from the study at any time. This will have no influence on your participation in any other research, or any other services you are currently receiving. You can stop the study at any time without any sanction.

What happens when the research study stops?

After the research study stops, the results of the study will be published, and shared with healthcare bodies in the Ghana, Cote d'Ivoire and Cameroon and the wider international community for the purposes of making policy decisions with the Ministry of Health. We may store the information you provided indefinitely, and this may be used by other researchers for future studies. None of the information used by other researchers will be identifiable.

Who is organising and funding the research?

The European and Developing Countries Clinical Trials partnership are paying for the study. The study is being designed and coordinated by, the London School of Hygiene & Tropical Medicine.

Who has reviewed the study?

[**ONCE APPROVED:** This study was given a favourable ethical opinion by the London School of Hygiene & Tropical Medicine Research Ethics Committee and the National Health and Research Ethics Committee.]

Contact Details

Should you have any questions or worries about the project, please feel free to contact any one of the study investigators:

Rebecca Handley (Study coordinator) Rebecca.handley1@lshtm.ac.uk +44207 927 2866
Michael Marks (Principle investigator) Michael.marks@lshtm.ac.uk +44207 927 2457

CONSENT SIGNATURE FORM – SUB-STUDY 4

Stick ID barcode label here

Title of Research:

Loop mediated isothermal amplification test development, implementation and evaluation for yaws eradication

Statement

- ☐ I have read the information on this study/research or have had it translated into a language I understand. I have also talked it over with the interviewer to my satisfaction and my questions concerning this study have been answered.
- ☐ I understand that my (my child's) participation is voluntary. I understand I may withdraw from the study at any time without giving a reason and that this will not affect my (my child's) normal care.
- ☐ I understand that the information collected about me (my child) will be used to support other research in the future, and may be shared anonymously with other researchers, for their ethically-approved projects.
- ☐ I give consent to be recorded for this study
- ☐ I know enough about the above named study and agree to take part.

To check appropriate one:

☐ *(A) Participant:*

NAME OF PARTICIPANT_____

SIGNATURE/THUMB PRINT OF PARTICIPANT: _____

☐ (B) *If participant is under 18 years)*

GUARDIAN'S NAME:_____

GUARDIAN'SSIGNATURE/*THUMBPRINT*: _____

RELATIONSHIP TO THE CHILD: [ ] FATHER [ ] MOTHER [ ] OTHER

Witness: I have read this form and the information form to the above person and am sure that he/she has understood what is required of someone enrolling in this study and they agree to enroll in the study.

Signed:…… Date:……