Feasibility and Accuracy of Nanosensor-based Cancer Diagnosis at the Point-of-care (Chedza)

NCT04119154

Informed Consent Form
Version 1.0, 17 July 2019

Protocol Title:
Feasibility and accuracy of nanosensor-based cancer diagnosis at the point-of-care
Principal Investigator:
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Description of Study Population: Individuals with possible cancer in Botswana
Version Date: 1.0, 17 July 2019

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because your health provider feels that you need a biopsy or aspiration to know if you could have cancer.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

Making a diagnosis of cancer can take a long time and this makes cancer much harder to treat. We want to understand if a new way of making a diagnosis is accurate and could be done in easily clinics in Botswana. We call the instrument that we are testing the CEM.

How long will I take part in this research?

Today's visit will take about 45 minutes. We will read your health records and ask you some questions.

You will be asked to allow us to test some of the fluid that the doctor takes from you. If you choose to participate, your doctor would take less than a teaspoon of additional fluid. The clinic or hospital

will do all the standard tests, but we will also test the fluid using the CEM. We may also perform a second review of your testing to confirm the diagnosis made by the pathologist.

Because we want to know what your doctor determines is the cause of your symptoms, we may need to call or visit you in the future. This would take less than 5 minutes.

More detailed information about the study procedures can be found under the *"What can I expect if I take part in this research?"* section.

Is there any way being in this study could be bad for me?

Your health provider will probably need to make additional insertions with the needle for the research. This may slightly increase the pain from the test and the chance of bleeding or other problems.

More detailed information about the risks of this study can be found under the *"What are the risks and possible discomforts?"* section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits may include confirmation of your diagnosis by a second reviewer.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.
Your alternative to participating in this research study is to not participate. Your diagnosis would be determined only by the standard way.

Detailed Information

To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you decide to participate in this research you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team: Isaac Nkele, lead research nurse at 72331114
Dr. Mompati Mmalane, physician investigator at 3902671.

The Health Research & Development Committee of the Botswana Ministry of Health approved this study. If you wish to speak with someone there about your rights as a research subject, please contact Chief Research Officer (phone: 363-2775)

Participation is voluntary

You are invited to take part in this research because your health provider feels that you need a biopsy or aspiration to know if you could have cancer. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

How many people will take part in this research?

About 350 people will take part in this research.

What can I expect if I take part in this research?

There would be three parts to your participation in the research. We expect that joining the study would take about 45 minutes of your time and your willingness to talk to us on the phone in the future.

First, we will make copies of your health records and ask you some questions. We want to understand the symptoms and medical tests that led your health care provider to think you needed testing for cancer. We also want to understand and record what other illnesses that you may have. You can skip any questions you don't want to answer.

Second, during your biopsy or aspiration procedure your doctor will take some additional fluid for us to test later in the new CEM instrument. The amount of extra fluid would be less than a teaspoon and your doctor will probably need to make one to three extra insertions of the needle to get this

fluid. Because we do not yet know if the CEM can give an accurate answer, we will not give you or your doctor the result that CEM gives us. We hope that in the future we can give patients the result the same day they have the test, but we can't do this until we know that it is accurate.

Third, we will stay in contact with you for up to a year and try to assist you in finding out what is the cause of your symptoms. This will mostly be done with phone calls lasting about 5 minutes but could involve meeting you in person at a clinic or in your home if we can't reach you. Your biopsy may be reviewed by a pathologist (a doctor that makes diagnoses by looking at biopsy under a microscope) in the United States. If they feel that the diagnosis is different, this will be communicated to your doctors so that they can determine how best to treat you.

What are my responsibilities?

As a participant, you are responsible for answering questions as honestly as you can, permitting us to review your records, permitting us to take extra fluid from you during your test, and allowing us to contact you in the future. We also would like you to tell us if any part of study makes you uncomfortable.

What are the risks and possible discomforts?

During your cancer test, your doctor will probably need to make additional insertions with the needle for the research. This may make it hurt more. The risk of bleeding or puncturing an organ is low from the procedure you are having. The additional insertions for research may increase this slightly.

You may feel worried or embarrassed when answering questions about yourself and your medical history. We will protect this information carefully, but there is a small chance of it being accidentally released.

Are there any benefits from being in this research study?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits may include confirmation of your diagnosis by a second pathologist and assistance in getting your test results and follow-up.

The knowledge gained from this research could help improve cancer testing. We hope that future people could obtain their diagnosis faster and more accurately the CEM. Your participation could help patients in the future.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

If you decide to leave the research, there would be no bad effects to you or to making a diagnosis. If you decide to leave the research, contact the investigator so that the investigator can ensure that we do not contact you again and so we know why you want to leave.

If you withdraw from the study, you will no longer be able to participate in the study. No new information or samples will be collected about you or from you by the study team. Information and your samples already collected will be kept.

Can I still get medical care if I choose not to participate in this research*?*
Yes, you may still get medical care if you choose not to participate in this study. Your decision will not change the care you receive now or in the future. Taking part in this research is your choice. If you decide to take part in this study, you may leave/stop the study at any time. There will be no penalty to you and your medical care will not be affected. If you would like to stop participating in this research you should let us know. We will make sure that you stop the study safely.

Will I be compensated for participating in this research?
You will get 50 pula in compensation for your time spent on the study.

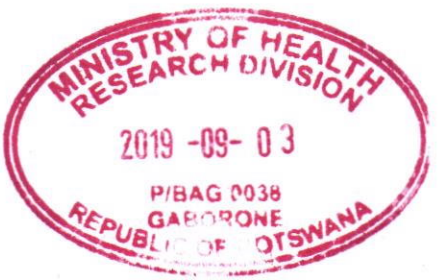
What will I have to pay for if I participate in this research?
There are no costs to you.

What happens if I am injured as a result of participating in this research study?
You will be referred to local government services if needed. There will be no costs for this treatment. In making a referral, or giving treatment, the persons doing the research do not admit that your injury was their fault. There is no program through BHP or the sponsors to pay you for your injury, but that does not affect the legal rights you may have as a result of such an injury. By signing this form, you will not be giving up any of your legal rights.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?
We will find a private place to talk to you. We will not talk to others about the answers you give us.

Your records will be confidential. Data collected, including identifiable health information, may be seen by the study team and the groups overseeing the study (such committees that protect the safety and rights of research volunteers; the Botswana Ministry of Health; the study sponsors; or monitors checking the study). Your information will be given a study code number. Files that link your name to the code will be stored with high-level security. Paper files with your name on them will be stored safely, separate from your survey answers or other health details. Study computers are protected. Study data shared with other researchers will not have your name on it. You will not be named in any publication or presentation from this study.

There may be tests that cannot be done in the lab in Botswana. Some samples may be sent elsewhere for testing. Your samples will not have your name on them. Your identity will be protected.



What else do I need to know?
This research is being funded by National Cancer Institute of the United States.

An aim of this study is to translate research findings to society through partnerships with industry. It is possible that a commercial product will ultimately be developed based on this current research. The sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples and information are used for this purpose.

Permission to Take Part in a Human Research Study

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

PARTICIPANT SIGNATURE:

Your signature below indicates your permission to take part in this research.

Name of participant (print)	Omang number
Signature of participant	Date
Printed name of person obtaining consent	
Signature of person obtaining consent	Date

WITNESS STATEMENT AND SIGNATURE: (only required when the participant or participant's parent/guardian cannot read the consent/assent form)

My signature and date indicates that the information in this form was accurately explained to, and apparently understood by the participant and that informed consent was freely given.

Name of witness (print)	
Signature of witness	Date