

Safety and Tolerability of Metformin in People with Tuberculosis (TB)
and Human Immunodeficiency Virus (HIV) (METHOD)

NCT04930744

HIV Informed Consent Form-Form 1

Document Date: 22 February 2024

**PARTICIPANT INFORMATION LEAFLET AND INFORMED CONSENT FOR HIV TESTING TO
BE DONE AS PART OF THE METHOD CLINICAL TRIAL**

Each participant should receive, read and understand this document
before any study-related procedure is conducted.

STUDY CODE: AUR1-1-199

STUDY TITLE: A Prospective, Randomized Open-Label Phase 2A Study of the Safety and Tolerability of Metformin in Combination with Standard Antimicrobial Treatment of Pulmonary Tuberculosis in People Co-infected with HIV

FUNDER: National Institutes of Health, National Institute of Allergy, Immunology and Infectious Disease, Division of AIDS

SPONSOR: THE AURUM INSTITUTE

INVESTIGATOR: (Name of Investigator)

INSTITUTION: (Name of Institution)

STUDY SITE CONTACT DETAILS:

AFTER HOURS: 000 000 0000

DAYTIME TELEPHONE NUMBER(S): 000 000 0000

To the potential Participant: *This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.*

(This Information Sheet will be available in local languages)

PARTICIPANT INFORMATION LEAFLET AND INFORMED CONSENT FOR HIV TESTING TO BE DONE AS PART OF THE METHOD CLINICAL TRIAL

INTRODUCTION AND PURPOSE

Good day! My name is _____ (Insert name of study staff), I work at (Insert name of Institution/Department). You have been invited to participate in METHOD, a study of additional medicines in the treatment of tuberculosis. The research study involves testing you for HIV. It is important that we know your HIV status first, so we know if you are okay to be in the main study.

This clinical study protocol has been submitted to the University of the Witwatersrand, Human Research Ethics Committee (HREC) and written approval has been granted by that committee.

The Human Immunodeficiency Virus (HIV) is a virus that causes Acquired Immunodeficiency Syndrome (AIDS). This is a condition in humans in which the immune system, the system the body uses to fight disease, begins to fail. This leads to other life-threatening infections, which the body would normally be able to fight.

Infection with HIV happens when a person without HIV comes into contact with an HIV-infected person's blood, semen, vaginal fluid, or breast milk. The three major ways of getting HIV are unprotected sex, contaminated needles, and spread from an infected mother to her baby at birth, or through breast milk.

HIV can harm the body's ability to fight infection. If HIV is not treated most patients get sick and may die. People with HIV are treated with medicines called anti-retrovirals. These may help people with HIV live longer. HIV positive people who manage their sickness and seek medical treatment can still live healthy and productive lives.

STUDY PROCEDURES

This study is testing a new treatment for TB in people living with HIV/AIDS. It is necessary to test you for HIV because persons without HIV infection cannot participate in the trial.

You do not have to take this HIV test, it is voluntary. However, if you refuse you will not be able to continue in this research study. In addition, your refusal will not affect your access to other medical care available to you.

POSSIBLE RISKS AND INCONVENIENCES OF BEING IN THE STUDY

At the needle/injection site you may feel discomfort, see bruising and bleeding. More rarely you may have infection and fainting.

The disadvantages of taking an HIV test (especially if the result is positive) are possible rejection and discrimination by friends, family and colleagues, emotional problems, increased stress levels and an uncertainty about the future.

POSSIBLE BENEFITS OF BEING IN THE STUDY

There are advantages of knowing your HIV status. If you test negative, you may feel less anxious after knowing your HIV status, and may take steps to protect yourself against infection. If you know you are HIV positive, it may reduce the stress that comes with the uncertainty of not knowing. You can take advantage of treating your HIV early, monitoring your health, eating well and healthily. You will also know whether or not you can infect others and what to do to prevent this from happening. Women and their partners thinking about pregnancy can take advantage of treatments that can help prevent their baby getting HIV. You can also possibly plan for future care

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of your children. Testing and knowing if you are positive can help HIV positive people manage their sickness and seek medical treatment. These people can still live healthy and productive lives.

COUNSELLING BEFORE AND AFTER TESTING

You will be asked to participate in a counseling (short private talk) with study personnel before the blood sample for HIV testing is obtained, so that you better understand what will be done. You will also be asked to participate in a short private talk with study personnel after your results become available, so that you better understand what they mean.

COMPENSATION IN THE EVENT OF A TRIAL RELATED INJURY

The blood sample is covered by insurance coverage taken out by the sponsor (The Aurum Institute) and also by the study team according to the laws and regulations of the country in which the study is done (for more details, see the information sheet describing the main clinical study).

CONFIDENTIALITY

Your confidentiality will be kept and only the study doctor and research team will be aware of the results. Selected people working for the sponsor and representatives of government regulatory authorities and ethics committees will also have access to the results. These persons are required to keep your information confidential. By signing this document, you are authorizing this access.

PAYMENT, EXPENSES AND COSTS

You will be given the chance to receive counseling before and/or after the HIV test has been done. Please tell the site staff if you wish to receive counseling or not. There will be no cost to you. We will provide the counselling and the HIV test.

Should you test positive, the sponsor or study site will not be liable to you for any payments related to your HIV. You will be referred to a local HIV clinic for more testing and counseling.

CONTACTS FOR ANSWERS RELATED TO THE RESEARCH, YOUR RIGHTS AND IN THE EVENT OF AN INJURY

You will be under the care of (Insert Investigator name). If you have any problems or questions during the HIV testing part of the study, please contact your study doctor (above) or one of the other study doctors working on this study.

The 24-hour telephone numbers with which you can reach your study doctor or another authorized person is: Telephone number (Insert Contact Number).

If you want any further information regarding your rights as a research participant, or have any complaints regarding this research study, you may contact Prof Ruff, Chairperson of the University of Witwatersrand, Human Research Ethics Committee (HREC), which is an independent group that helps protect the rights of research participants at (011) 717 2301 or email: EthicsRegulatory@witshealth.co.za.

If you have questions about this trial, you should first discuss them with your study doctor or the above-mentioned ethics committee. After you have consulted your study doctor or the ethics committee and if they have not provided you with answers to your satisfaction, you should write to the South African Health Products Regulatory Authority (SAHPRA) at:

METHOD

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The Chief Executive Officer
South African Health Products Regulatory Authority
Loftus Park, Building A, 402 Kirkness Street
Arcadia, Pretoria, 0083
E-mail: Boitumelo.Semete@sahpra.org.za
Tel: 012 501 0413

- If applicable, if you have any complaints regarding the protection of your information in this study, you may submit such complaints to the Data Protection Officer for the site, on the abovementioned contact details.
- You may also contact the Sponsor Data Protection Officer for the study, Ms Marlize Pistorius at: Tel (contact number): +27 (0) 87 135 1684 or dpo@auruminstitute.org.

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CONSENT STATEMENT FOR HIV TESTING

By signing below, I agree that:

- I have read and understand the information sheet and consent form for HIV testing.
- I have had the chance to ask questions and they were answered to my satisfaction.
- I have been given the time to discuss the information with others and to decide whether or not to take part.
- I will be offered a signed and dated copy of this consent form on the day of my signing it for me to take with me when I leave today.

I voluntarily agree for HIV testing to be performed.

Participant's Name (print) In full as per ID Document	Participant's signature/mark/thumbprint	Date	Time
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TRANSLATOR (If applicable):

Translator's Name (print) In full as per ID Document	Translator's signature	Date	Time
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WITNESS (If applicable):

Witness' Name (print) In full as per ID Document	Witness signature	Date	Time
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STUDY STAFF

I, herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

Name of Study staff member obtaining consent (print)	Study staff signature	Date	Time
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