

endTB Clinical Trial
Research Screening Adult Consent Form

Version 3.3 Version Date: 14 February 2019

Subject Identification

Protocol Title: endTB (Evaluating Newly approved Drugs for multidrug-resistant TB)

Sponsor: Médecins Sans Frontières (Doctors Without Borders) - France

Principal Investigators: Carole Mitnick, Sc.D. and Lorenzo Guglielmetti, M.D.

Site Principal Investigator: [Insert PI Name]

Research Center: [Insert Research Center Name]

Participant Name (please print): _____

Study Subject ID: _____

About this consent form

You have been diagnosed with multidrug-resistant tuberculosis (MDR-TB). We are conducting a study, called endTB, to see whether we can find a better treatment for MDR-TB. We would like to ask you whether you agree to be interviewed and examined to see whether you could be in our study.

Please read this form, called research screening consent form, carefully. It tells you important information about evaluating you for participation in the endTB study. This evaluation is called “screening”. A member of our research team will talk to you about what it means to take part in the screening. People who agree to take part in screening are called “participants” in this consent form.

Introduction

TB is a disease caused by bacteria (or germ) that usually affects the lungs. It is passed from person to person through the air by droplets that come from the lungs of a person who is sick with TB. When the sick person coughs, sings, shouts, or spits, the TB bacteria can make others sick. Most people with TB can be treated and cured, if they complete all their treatment. Some types of TB bacteria cannot be killed by the regular drugs (rifampicin and isoniazid). These bacteria are called multidrug-resistant. People sick with multidrug-resistant TB need different drugs for their treatment.

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We are asking you to be screened for the endTB study because you are at least [18] years old and you have MDR-TB that is affecting your lungs. During this screening, we will do some laboratory tests and a doctor will examine you to see if you are eligible to be in the study. At least 2000 patients in 7 countries will be screened for this study. We expect about [number to be adapted locally] patients will be screened at [Research Center Name].

Médecins Sans Frontières (Doctors Without Borders) –France is the sponsor of this study.

If you have any questions about the screening or about this form, please ask us. Taking part in the screening for this study is up to you. You do not have to be screened if you do not want to. Screening is the first step. If you would like to take part in this screening, we will ask that you sign this form to confirm that you accept to be screened to see if you are eligible to be in the study. We will give you a signed copy of this research screening consent form to keep. You can decide not to take part in this screening at any time if you do not want to, even after signing this form.

If you are not able to sign the consent form, but you would like to participate, you can choose someone you know to sign for you and you can make a thumbprint to show that you understand the study and would like to be screened.

If you agree to be screened and are eligible to be in the study, we will give you more information about the study and ask you to sign another form to show you agree to take part in the study.

Why is this study being done?

Current treatment for MDR-TB includes 5-9 drugs taken daily for 18 to 24 months. During at least six months, treatment includes a daily shot. This treatment may cause many mild and very serious side effects, for example: nausea, vomiting, hearing loss, numbness/tingling in fingers and toes, kidney damage, mental illness/feeling sad, etc. Two new drugs (delamanid and bedaquiline) have recently become available. New regimens containing one of these drugs may be shorter for example, 9 months and/or simpler (without injection). Such regimens have to be tested to see if they are safe and effective for people with multidrug-resistant TB. We are asking to screen you for a study to test new 9-month-long, injection-free MDR-TB treatments. This research trial will compare new experimental treatment regimens to the current treatment for MDR-TB.

How long will the screening process take?

The complete screening process for this study could take 4 to 5 hours of your time. However, it is possible the doctors will need to see you at separate visits to finish all the screening procedures. If that happens, all visits should be done within 2 weeks.

What will happen during screening?

We will ask you to come to [Research Center Name]. We will ask you to sign this consent form before we do any screening procedures. Then, we will do some tests and procedures to see if you are eligible to take part in the study. The study doctor will review the results of these tests and

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procedures. If you cannot participate, the study doctor will tell you why and might ask if you will participate in another study.

Specifically, during screening, we will:

1. Answer all your questions and get your permission for screening.
2. Ask for your full name, contact information, sex, and age.
3. Review your medical history, including past or present illnesses, and information on drugs you are currently taking.

The treatment you will receive for your TB may interact with some of the drugs that you are currently taking. The study doctor may review with you if some of your drugs need to be stopped or changed prior to receiving any MDR-TB treatment.

4. Perform a complete check-up and ask about your TB symptoms.
5. Collect 2 tablespoons of your blood for laboratory testing to check if your body is functioning well.
6. Unless recent results are available, we will also ask you to use the collected blood for viruses that might affect your treatment for TB, like hepatitis B and C, which affect your liver, and HIV, which affects your body's ability to fight infection.

All test results will remain confidential. You have the right to decline these tests. Declining a test will not affect your participation to the study and the access to usual treatments that do not depend on knowledge of the test result. If the test result(s) is positive, you will be referred to appropriate care. If you have HIV infection, we will test CD4 count and HIV viral load to see if the disease is well controlled.

7. Ask you to cough up 3 sputum (or phlegm) samples. These will be used to test whether the TB bacteria can be treated with regular drugs and/or drugs in the study treatments. This is called testing for drug resistance.
8. Do a test, called an electrocardiogram, to check if your heart works normally.
9. Because we don't know if some of these medications are safe in pregnancy:
 - The study doctor will discuss birth control methods to avoid pregnancy (yourself or your partner) if you are eligible and agree to participate in the study.
 - Pregnant patients cannot enter the study. So, if you are a woman who can get pregnant, we will collect a urine or blood sample for a pregnancy test. Your study doctor will refer you to for TB treatment outside of the study if the test shows you are pregnant.

Depending on your test results:

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- your study doctor may prescribe medications, for example to balance the level of salts in your blood, when possible;
- some of these tests may need to be repeated within the 2-week period; your study doctor will let you know which ones.

We will label all your samples and health information with a code instead of your name to keep all your information private. The key to the code connects your name to your samples and health information. The study doctor will keep the key to the code in a password-protected computer and/or locked file.

Storing Isolates (strains) and Health Information for Future Research

We would like to store some of the bacteria isolates (TB bug), and health information for future research related to TB, which will be collected during this screening. All your health information and bacteria isolates will be handled in a way to keep all your information private. Any use of stored bacteria isolates and your health information for other research inside your country or in other countries will be approved by the ethics committee of your country.

This future research is independent from being screened for the endTB study and your decision to participate in the future research will not affect your participation in the screening for endTB study.

The bacteria isolates found in your sputum samples and your health information may be stored for up to 20 years in a special place (bank or repository) created to safely store them. The stored isolates and your health information will be used only to help future research in TB and to improve diagnosis (including resistance testing) and treatment of TB. During your participation in the endTB study, and the following storage period of 20 years after completion of the study, you can contact your study doctor or the email address endTB.clinicaltrial@paris.msf.org to request any information regarding the use, storage and location of your health information and bacteria isolates.

Do you agree that your health information and bacteria isolates found in your sputum samples may be stored for 20 years and used only for future TB research? You are free to refuse such storage and further use for TB research of your health information and bacteria isolates and still take part in this screening.

☐ Yes ☐ No [Initials or signature, to be adapted locally]_____

You have the right to change your mind, and to later want your health information and/or bacteria isolates destroyed. In that case, during your participation in the endTB study, and the following storage period of 20 years after completion of the study, you can contact your study doctor or the email address endTB.clinicaltrial@paris.msf.org to request any information regarding the use, storage and location of your health information and bacteria isolates and/or their destruction.

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What are the risks and possible discomforts from being screened for this study?

Risks of Blood Draws

You may have a bruise (a black and blue mark) or pain where we take the blood samples. There is also a small risk of infection, light-headedness, and/or fainting.

What are the possible benefits from being screened for this study?

This screening evaluation has not been designed to give you direct benefits but it may help you to get treatment within the study, or get other appropriate treatment more quickly. Others with MDR-TB may benefit in the future from what we learn in this study.

Can I still receive TB treatment if I do not take part in this screening?

Yes. You will receive treatment through [local TB care provider/entity] if you do not take part in this screening. Taking part in this screening is up to you. You can decide not to take part. There will be no penalty, and you will not lose any benefits you receive now or have a right to receive.

What should I do if I want to stop taking part in this screening?

If you give your agreement for the screening, and you change your mind you should tell us.

Also, it is possible that we will have to ask you to drop out of the screening before you finish it. If this happens, we will tell you why.

And, we will tell you if we learn any new information that could make you change your mind and drop out later.

In any of these cases, we will discuss with you and refer you to other care, if needed.

Information collected during your screening will be used to help answer study questions. When you leave the study, your health information, and information obtained from sputum samples and bacteria isolates previously collected may still be used and stored for 20 years for the study and future TB research. However, if you prefer that this information is not used and that it is destroyed, you can contact your study doctor or the email address endTB.clinicaltrial@paris.msf.org.

Will I be paid to take part in this screening?

You will not be paid to take part in this screening. However, we will cover transportation costs for visiting the research center(s). We will pay or you will be reimbursed [local currency] _____ for transportation to and from the screening visit.

What will I have to pay for if I take part in this screening?

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All screening procedures will be free of charge to you.

What happens if I am injured as a result of taking part in this screening?

If you suffer physical injury from the screening, _____ will give you immediate medical treatment.

_____ will not pay to treat a medical condition or disease you had before screening or expenses for injury, treatment, or hospitalization you may require that are not the result of your participation in the screening.

You do not waive any of your legal rights by signing this consent form.

Who can I speak to if I have questions, concerns or complaints?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want

[PI Name and title] is the person in charge of the screening and study. You can call him/her at [PI telephone number]. You can also call [Clinical Investigator] at [CI number] with questions. If you have questions about the scheduling of appointments or study visits, call [Study Coordinator] at [SC number].

If you want to speak with someone not directly involved in the screening or study, please contact the [Research Center IRB] office. You can call them at [Research Center IRB number].

If I take part in this screening, how will you protect my privacy?

We are careful to protect the identities of the people who are screened in this study to the extent permitted by law. We also keep your information secure and confidential. Electronic study information will be password-protected, and paper files will be stored in a locked office at [Research site]. Your screening records will be kept at the clinic/hospital for XX years [to be adapted locally] following the completion of the study. If needed to monitor the study quality, your information may be looked at by institutions responsible for quality and privacy such as the sponsor, Ethics Committee and Competent Authorities.

For the screening, we will store some non-medical information about you, such as your date of birth and city of residence. You can ask us to access, modify, complete, update, or delete this information. If you have any complaints about the protection of your data, you could contact your local/national Data Protection Authority [Name and contact to be adapted locally].

The information collected for screening will be used for the following purposes:

- For the purposes of this study. The sponsor, the study doctor, or other doctors involved in the study may publish reports or articles on the screening or present

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screening findings to scientific groups. After the study is completed, you may see your records, and you may be told the results of the study.

- Secondary use for TB research; your coded information may be used and shared with other institutions only for the purpose of further TB research during and after completion of the study and notably with the World Health Organization.

In all cases your identity will never be disclosed.

Your coded information may be sent electronically to other researchers or institutions. If sent, it will be encrypted (scrambled so it cannot be read by people who should not see it).

We guarantee that, when we send your coded information, it will be protected according to European Economic Area standards.

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Informed Consent and Authorization

Your signature on this document means the following:

I have read this consent form. The screening process has been explained to me, including risks and possible benefits, other possible treatments or procedures, and other important things about the study. I have had the opportunity to ask questions. I understand the information given to me. I recognize that my participation is voluntary and that I can refuse or end my participation at any time, without any loss of benefits that I would otherwise have.

I recognize that by signing this document, I do not lose any of my legal rights as a participant. I will receive a complete, signed, dated copy of this research screening consent form.

By signing below, I agree to take part in the screening.

Signature of Participant

Signature or thumbprint of participant

Date (DD/MMM/YYYY) and Time

Name of participant, printed in capital letters

Witness (if applicable):

Signature of witness

Date (DD/MMM/YYYY) and Time

Name of witness, printed in capital letters

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Study representative who obtained informed consent:

I have explained this study to the participant and have answered all of his/her questions. He/she understands the information described in this document and accepts voluntary participation in the study.

Signature of study representative
and Time

Date (DD/MMM/YYYY)

Name of study representative, printed in capital letters