RESEARCH INFORMATION AND CONSENT FORM

GXT - GeneXpert Or Chest x-rays OR Tuberculin Testing for HouseHold contact Assessment – a cluster randomized trial

Persons responsible :

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WHY ARE YOU BEING INVITED TO TAKE PART IN THIS STUDY?

This hospital/clinic participates in research studies to try to improve how care is provided for different types of illnesses. Today, we are inviting you to take part in a research study. Please read this information to help you decide if you want to participate in this research project. It is important that you understand this information. We encourage you to ask questions. Please take all the time you need to make your decision.

This study will include both adults and children. We encourage parents to include their child in the discussion and decision making to the extent that the child is able to understand.

In this research information and consent form, "you" means you or, if you are giving consent for a child, your child.

We are asking you to participate in this research study because you have been in close contact with a person who has pulmonary active tuberculosis (TB). Because of this exposure, you may have been infected with the tuberculosis germ. This germ could make you sick right away with TB disease, or you may now have "latent" TB. Latent TB is an infection that does not make you feel sick or unwell right now, but it could make sick with TB disease later if you are not given treatment for it.

WHY IS THIS STUDY BEING DONE?

If a person is exposed to someone who has TB through close contact, such as living in the same household, we call them "contacts". Identifying and doing tests on (or investigating) "contacts" is a very effective strategy to increase

the number of people who are found to have active TB or latent TB, so that they can start treatment. The procedure that is currently used to investigate if contacts have TB disease or latent TB is based on what the World Health Organization recommends - people are to be asked about any symptoms that they might have, to do a tuberculin skin test (called TST) and, if needed, to do a chest x-ray (CXR). However, in some countries, it is difficult for clinics to have access to materials to do a TST and to provide a CXR to all contacts who need them. As a result, in many countries contacts are not properly tested and many people who could have TB disease or latent TB are not treated.

We are doing this study because we want to find the best way to test people for active TB or latent TB after they have been in close contact with someone who has active TB. In the study, we will be able to gather information from people in settings where TST and CXR are not always available.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About **1450** participants from clinics in Rio de Janeiro, Brazil and Cotonou, Benin will take part in this research study.

WHAT WILL HAPPEN IN THIS RESEARCH STUDY?

In this study three different approaches will be compared to test for active TB and latent TB. These approaches include different combinations of three tests: TST, CXR and GeneXpert MTB/RIF (GX). (performed on sputum samples). None of the tests used in this study are new. They are all well known and widely used in TB programmes in many countries throughout the world – including Brazil and Benin where this study will be conducted. What is new about this study is the way in which these tests are combined. We will compare which approaches to testing work best to detect active TB and latent TB, and how much each of the approaches costs patients and their families.

1) The first approach is the “standard way” - contacts will be asked about TB symptoms and a TST will be provided to all contacts. A CXR will also be given to those who need it.

2) For the second approach contacts will be asked about TB symptoms and will have a TST. Instead of the CXR a sputum test (GeneXpert (GX)), will be performed for those who need it. The GeneXpert is a test that detects in the sputum (spit) the bacteria that cause TB. This test can provide results within 2 hours, and is quite accurate, but is also costly, and so not available in many hospitals/clinics.

3) For the third approach contacts will be asked about TB symptoms and will have a CXR, but will not have a TST.

If you agree to take part in this study, you will be randomized to one of the three approaches to testing. The choice of which approach you will be following will be made by chance (like flipping a coin). Neither you nor your doctor or the researcher will choose which approach you will be part of. This is called “randomization”.

In all three of the approaches your doctor will first check if you have any symptoms of TB. Then, depending on the approach you will be in, you will be asked to:

1. do a TST and then, if needed, have a CXR (if in approach 1 described above), or
2. do a TST and then, if needed, have a sputum exam that uses the GeneXpert (if in approach 2); or
3. do only a CXR (if in approach 3).

Based on the results of these tests, you could be asked to do further tests (for example you could be asked to do another sputum exam, or take an CXR, even if you were in approach 2), just to make sure you do not have TB disease.

At the end of the investigations in all of the approaches, your doctor would either tell you that you are healthy and do not need to take any kind of treatment, or that you have (or that you are at high risk of having) latent TB and you will receive treatment for latent TB. You may also be told that you have TB disease and you will receive treatment for active TB. If you require treatment for latent TB or active TB, then your doctor will prescribe the treatment that is usually recommended by the TB program in your country. If other diseases are suspected during the investigation, your doctor can order additional tests and may prescribe other non-TB related medications, if she/he feels these are needed.

The research team will consult your medical record to obtain information relevant to this research.

If your doctor prescribes treatment for you, you will be followed by the clinical team in the usual way, but it is important that you BRING YOUR BOTTLE of medication at every visit. At each visit, the clinical team will ask you about the treatment and whether you are having any difficulties taking it and will examine you. As well, blood tests will be performed according to standard practice if your doctor feels this is necessary.

FOR HOW LONG WILL YOU PARTICIPATE IN THIS STUDY?

Your involvement in this study will vary depending on what is found during the initial investigation. If you do not have to take any treatment, you will only participate for a maximum of 3 months which is about the amount of time it takes to complete the tests that will be conducted as part of a contact investigation. If you have to take treatment for active TB or latent TB, you will be followed until the end of your treatment (usually about 6 months time).

WHAT ARE THE RISKS?

Approaches 2 and 3 are new strategies that we are testing in this study. This means that we do not know whether following either of these two new alternative approaches will allow us to correctly identify and treat all contacts that should be treated for active TB or latent TB. This means that some contacts could receive treatment for latent TB when they don't need it, or are treated for latent TB when they actually have active TB. But, from other studies done so far, we think that the chance of this happening is minimal and that, with any of the three strategies, the great majority of the contacts should be correctly classified as "not needing any treatment", "needing latent TB treatment" or "needing active TB treatment".

RISKS ASSOCIATED WITH PREGNANCY

Female participants of childbearing age will be questioned regarding possible pregnancy, and if pregnancy is confirmed (or possible) and a CXR is considered necessary (according to the study protocol), CXR should be used with appropriate shielding.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

By taking part in this research study you can help us learn more about the best way to investigate active TB and latent TB in contacts of individuals with active TB . There is no other specific reason or advantage to taking part in this study.

WHAT OTHER OPTIONS ARE THERE?

If you choose not to take part in this study, you will receive the standard investigations that are normally conducted by your clinical team. You do not have to participate in this study to to be investigated for active TB and latent TB.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You will not have to pay for any tests that are used during investigations, such as the tuberculin skin test, Chest x-ray or the GeneXpert. The costs associated with these tests will be paid for by the research study. Medications for latent TB or active TB, if needed, will be also provided at no cost by the National TB program in your country.

ARE THERE OTHER FINANCIAL ASPECTS?

You will not be reimbursed for other costs incurred during your participation.

HOW IS PRIVACY ENSURED?

All information obtained during the study will be kept confidential as required or permitted by law. Your identity will be protected by replacing your name with a research number. Only the research team at your own hospital will have access to the code linking your name to this number.

In order to ensure your protection and quality control of the research project, the following organizations could consult your research and medical records:

- The sponsor(s) of this project;
- The research ethics committees of the hospitals where the research is happening or a person mandated by one of them;

These organizations all adhere to a confidentiality policy.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

The principal investigator at your hospital will be responsible for securely storing all research data for 7 years. Only coded data will be stored.

IS YOUR PARTICIPATION VOLUNTARY?

Your participation in this research project is voluntary. Therefore, you may refuse to participate. You may also withdraw from the project at any time, without giving any reason, by informing the study doctor or a member of the research team.

Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with your doctor or clinical team.

The study doctor, the Research Ethics Board, the funding agency, or the Sponsor may put an end to your participation without your consent. This may happen if new findings or information indicate that participation is no longer in your interest, if you do not follow study instructions, or if there are administrative reasons to terminate the project.

If you withdraw or are withdrawn from the study, the information already collected for the study will be stored, analyzed and used to ensure the integrity of the study.

Any new findings that could influence your decision to stay in the research project will be shared with you as soon as possible.

SHOULD YOU SUFFER ANY HARM

By agreeing to participate in this research project, you are not waiving any of your legal rights nor discharging the study doctor, the sponsor or the institution, of their civil and professional responsibilities.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions, either now or any time in the future, about this study, please feel free to discuss them with the people who are in charge of the study:

- McGill University Health Centre: Dr. Dick Menzies at 514-934-1934 ext:32128
- Rio de Janeiro, Brazil: Dr Anete Trajman at 51-XXXXXXX
- Cotonou, Bénin: Dr. Menonli Adjobimey at 229- XXXXXXX

In case of emergency, please go directly to the closest emergency room.

If you would like information about your rights related to your participation in the research, you may contact the hospital Ombudsman (Patient Representative):

- McGill University Health Centre: 514-934-1934 ext. 34329

WHERE CAN I GET MORE INFORMATION?

Feel free to ask any questions that you might have about the study and what you have just heard. You can ask now, or at any time once the study has started.

A description of this clinical trial will also be available on http://www.ClinicalTrials.gov. This Website will not include information that can identify you. You can search this website at any moment.

You may ask to receive a copy of the results of this research project; these will only available after the entire project has been completed.

You will receive a signed copy of this consent form. You may ask the research team questions at any time.

RESEARCH ETHICS COMMITTEE

The McGill University Health Centre Research Ethics Board reviewed this research and is responsible for monitoring the study.

CONSENT AND ASSENT FORM

Title of this research project: **GXT - GeneXpert Or Chest x-rays OR Tuberculin Testing for Household contact Assessment – a cluster randomized trial**

I have been explained what will happen on this study. I read the information and consent form including the annexes and was given a copy to keep. I was able to ask my questions and they were answered to my satisfaction. After thinking about it, I agree to, or I agree that my child will, participate in this research project.

I authorize the research team to consult my medical records or the medical records of my child to collect the information relevant to this project. I understand that a signed copy of this consent form will be given to me.

Name of participant < 18 (Print)	Assent of minor, capable of understanding the nature of the research (signature) or Verbal assent of minor obtained by: _____	Date
Name of parent(s) or legal guardian (Print)	Signature	Date
Name of participant (18 years +) (Print)	Signature	Date

I have explained to the participant and/or his parent/legal guardian all the relevant aspects of this study. I answered any questions they asked. I explained that participation in a research project is free and voluntary and that they are free to stop participating at any time they choose.

Name of Person obtaining consent (Print)	Signature	Date