



Title of Study:

Taima TB: 3HP Study (Iqaluit)

Principal Investigator (PI):

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A key element to control the spread of tuberculosis (TB) is treating latent TB infection (also known as 'sleeping TB') before it turns to active TB disease. Those with latent TB infection (LTBI) have TB but it is inactive. They are not sick and they are not contagious. However, without treatment this TB infection could cause a person to become sick with active TB disease. They could have a cough, fever, poor appetite and weight loss. Those with active TB disease might also be contagious and spread TB to others. This is why it is recommended that those with LTBI take treatment to get rid of the germs before it turns to active TB disease. If treated, the chance that LTBI will turn to active TB disease in the future is greatly reduced.

The main purpose of this study is to find out whether more people will start and finish treatment for latent TB infection if the treatment is shorter. Usually people with latent TB infection take *one* drug, INH. They have to take it twice a week for 9 months in Nunavut for a total of 78 doses. In this study, participants would take *two* drugs, rifapentine and INH, but only once a week for 3 months for a total of 12 doses. The combination of rifapentine and INH is called '3HP'. Research studies show that 3HP for 3 months works as well and is as safe as the usual treatment of INH for 9 months.

We are doing 3HP studies in Iqaluit and in Ottawa. For the Iqaluit study, we estimate that approximately 225 participants will be part of the study. Eligible individuals between the ages of 2 to 65 years living in Iqaluit who are diagnosed with LTBI will be given the option to have treatment with 3HP. The primary objective of this study is to compare the proportion of people who complete directly observed prophylactic treatment (DOPT) using the new 3HP regimen to the current standard of 9 months INH. We will also look at whether 3HP is more cost effective than the current treatment.

INH has been used to treat TB in Canada for over 40 years. Rifapentine is approved by the Food and Drug Administration (FDA) in the United States. It has not been approved for sale or use by Health Canada but we have gotten a 'No Objection Letter' from Health Canada to use it for this research study. We also have approval from the Ottawa Health Science Network Research Ethics Board to do this research in Iqaluit. The Taima TB steering committee, which is made up of representatives from Nunavut Tunngavik Inc, the Government of Nunavut, and the Ottawa Hospital Research Institute, has been guiding this project from idea to action. Funding has been provided by the First Nations and Inuit Health Branch of Health Canada and the Public Health Agency of Canada.