GXT – GeneXpert or chest-X-ray or Tuberculin skin testing for household contact assessment: a cluster randomized trial - Summary
clinicaltrial.gov: NCT04528823

Rationale: The objective of the study is to compare outcomes from three different strategies for the management of household (HH) contacts of individuals with newly diagnosed microbiologically confirmed active pulmonary TB. The study is a cluster randomized trial with three arms of equal size. The first eligible member of the HH who provides signed informed consent to participate will be randomized to one of the three strategies. The three different study arms are as follows:

1. Standard care (control arm): Participants will receive symptom screening and tuberculin skin testing (TST). If symptom screen positive and/or TST positive, they undergo chest x-rays (CXR). If CXR abnormal, they undergo microbiological investigation. If CXR normal or if microbiological investigation negative, TST positive receive latent TB infection (LTBI) treatment. If microbiological investigation is positive, they will be offered treatment for active TB.

2. GeneXpert (GX): Participants follow an algorithm similar to the standard care, however participants with positive symptom screen and/or positive TST will receive GX (i.e., GX replaces CXR in standard care algorithm). GX positive are considered to have active TB. TST positive and GX negative receive LTBI treatment. If an individual is not able to provide sputum, they will undergo a CXR.

3. CXR for all/NoTST: Participants will receive symptom screening and CXR. No TST will be performed. If CXR abnormal or symptom positive, they undergo microbiological investigation. If the CXR is normal, and/or microbiological investigations negative – they receive LTBI treatment as per national guidelines. If microbiological investigation is positive they will be offered treatment for active TB.

Population and setting: The study population includes HIV uninfected persons aged 5-50 years who are HH contacts of individuals with newly diagnosed microbiologically confirmed active pulmonary TB. The planned number of household contacts to recruit is about 1434 in total, or about 455 for each of the three arms. The study will take place in Benin and Brazil.

Primary outcomes: The primary study outcome is, of those eligible for LTBI therapy, the proportion starting therapy within 3 months of the index TB patient starting active TB treatment. Secondary outcomes measured in each study arm include societal costs, prevalence of microbiologically confirmed and clinically diagnosed active TB, prevalence of TB infection, Incidence of adverse events, completion of LTBI therapy, sensitivity and specificity of Chest Xray reading in each study side, and prevalence of active TB diagnosed using CXR in participants who cannot produce a sputum sample. Details of the statistical analysis plan for each primary and secondary outcome are provided below.

Study participants will be recruited over 18 months. Participants will be followed until LTBI treatment is completed.