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NIH launches large TB prevention trial

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For people exposed to multidrug-resistant TB

A large clinical trial to assess treatments for preventing people at high risk from developing multidrug-resistant tuberculosis (MDR-TB) has begun. The study is comparing the safety and efficacy of a new MDR-TB drug, delamanid, with the decades-old TB drug isoniazid for preventing active MDR-TB disease in children, adolescents and adults at high risk who are exposed to adult household members with MDR-TB.

Study participants are at high risk for MDR-TB because they either have latent TB infection, immune systems suppressed by HIV or other factors, or are younger than age 5 years and therefore have a weak immune system.

Delamanid is one of the first drugs available specifically to treat people with MDR-TB and the first to exist in a formulation suitable for children.

The study investigators hypothesize that prophylactic treatment with delamanid will prove better than isoniazid at reducing the likelihood that at-risk household members of individuals with MDR-TB will develop active TB disease. Isoniazid is the standard drug for TB prevention in many of the study's host countries.

The Phase 3 clinical trial is called PHOENIx MDR-TB, short for Protecting Households on Exposure to Newly Diagnosed Index Multidrug-Resistant Tuberculosis Patients. The study is co-funded by NIAID and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, also part of NIH. The AIDS Clinical Trials Group (ACTG) (link is external) and the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network (link is external), both funded by NIH, are conducting the PHOENIx MDR-TB study. The manufacturer of delamanid, Otsuka Pharmaceutical Co., Ltd. of Tokyo, is donating the drug to the trial.

The PHOENIx MDR-TB study will take place at more than 27 sites in at least 12 countries, including Botswana, Brazil, Haiti, India, Kenya, Peru, the Philippines, South Africa, Tanzania, Thailand, Uganda and Zimbabwe. The study team will enroll approximately 5,610 participants, including 2,158 adults ages 18 and older who are being treated for confirmed active MDR-TB through their country's national TB treatment program and 3,452 members of their households who are at high risk for

developing active TB disease.