

TUBERCULOSIS CLINICAL RESEARCH AT IDI

TB Diagnostics Clinical Trials

- ***Feasibility of Using the Inverness Lateral Flow Urine LAM Test for Diagnosis of Tuberculosis in HIV-Positive TB Suspects.*** A study to determine the accuracy, diagnostic yield, operational performance, and time to diagnosis of a novel lateral-flow urine lipoarabinomannan (LAM) test in detecting tuberculosis in HIV-infected adults. *Sponsor: Tuberculosis Clinical Diagnostics Research Consortium.*
- ***Novel diagnostic tests for TB in Uganda: Small Membrane Filtration Method (SMF) for diagnosis of TB.*** *Sponsor: Tuberculosis Clinical Diagnostics Research Consortium.*

Randomized Clinical Trials

Prevention of Early Mortality by Presumptive Tuberculosis (TB) Treatment (PrOMPT). A multi-site Phase IV study comparing early mortality in the group presumptively treated for TB in addition to ART versus standard of care. *Funder: EDCTP*

Clinical pharmacokinetics studies enrolling tuberculosis participants

- ***Evaluation of the pharmacokinetics of antituberculosis drugs and tuberculosis treatment outcomes in HIV-tuberculosis co-infected Ugandan adults.*** A 3-year phase IV study of the correlation of anti-tuberculosis drug concentrations and clinical response in HIV-infected individuals with pulmonary tuberculosis. *Funder: University of Zurich*
- ***Evaluating pharmacokinetic interactions between artemisinin-based therapies and rifampicin-based tuberculosis treatment in African patients.*** This ongoing project investigates drug interactions between rifampicin-based TB treatment versus dihydroartemisinin-piperaquine, artesunate-amodiaquine or intravenous artesunate. *Funder EDCTP.*
- ***Evaluation of the pharmacokinetic interaction between artemether/lumefantrine and rifampicin-based TB treatment.***
This study found that rifampicin-based TB treatment markedly lowers blood levels of artemether-lumefantrine. The findings of this study have resulted in a label change for Coartem[®] to indicate that co-administration of these drugs is contraindicated. *Funder: Trinity College Dublin/Haughton Institute.*
- ***Comparison of pharmacokinetics of nevirapine when initiated at 200 mg once daily or 200 mg twice daily in HIV/TB infected patients receiving rifampicin.***
This study investigated the effect of rifampicin treatment on plasma levels of nevirapine in HIV and TB co-infected adults at IDI. Rifampicin reduced nevirapine exposure and initiation of nevirapine without dose escalation is preferred. *Funder: University of Liverpool*

Vaccine site preparation study

AERAS – Uganda TB Vaccine Preparation Study. A prospective epidemiological study of tuberculosis in 2500 neonates in Iganga/Mayuge districts, Uganda, to determine the incidence of pulmonary tuberculosis. *Funder EDCTP.*

PUBLICATIONS

1. Hermans, S. M., Y. C. Manabe, et al. (2013). "Risk of tuberculosis after antiretroviral treatment initiation: a comparison between efavirenz and nevirapine using inverse probability weighting." *Antiviral therapy*.
2. Lamorde M, Byakika-Kibwika P, Mayito J, et al. *Lower Artemether, Dihydroartemisinin and Lumefantrine Concentrations during Rifampicin-Based Tuberculosis Treatment*. AIDS 2013; 27: 961-965
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4. Nakiyingi L, Kateete DP, Ocama P, Worodria W, Sempa JB, Asiimwe BB, Katabazi FA, Katamba A, Huang L, Joloba ML, Mayanja-Kizza H. *Evaluation of in-house PCR for diagnosis of smear-negative pulmonary tuberculosis in Kampala, Uganda*. BMC Research Notes 2012, 5:487, 5 September 2012
5. Sendagire I, Schim Van der Loeff M, Kambugu A, Konde-Lule J, Cobelens F. *Urban movement and alcohol intake strongly predict defaulting from tuberculosis treatment: an operational study*. Directorate of Health, Kampala Capital City Authority, Kampala, Uganda. PLoS One. 2012; 7(5) May 2.
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8. Yukari C. Manabe, Sabine M. Hermans, Mohammed Lamorde, Barbara Castelnovo, C. Daniel Mullins, Andreas Kuznik. *Rifampicin for Continuation Phase Tuberculosis Treatment in Uganda: A Cost-Effectiveness Analysis*. PLoS ONE, June 18 2012 | Volume 7 | Issue 6 |
9. Adithya Cattamanchi, Isaac Ssewenyana, Rose Nabatanzi, Cecily R. Miller, Saskia Den Boon, J. Lucian Davis, Alfred Andama, William Worodria, Samuel D. Yoo, Huyen Cao Laurence Huang. *Bronchoalveolar Lavage Enzyme-Linked Immunospot for Diagnosis of Smear-Negative Tuberculosis in HIV-Infected patients*. PLoS ONE, June 2012 | Volume 7 | Issue 6 | e39838
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improved HIV care: a retrospective cohort study. HIV Med, 2012, 5 Feb. DOI 10.1111/j.1468-1293.2011.00980.x

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