

Publications and Presentations of the Tuberculosis Trials Consortium (as of 1 February 2014)

I. Publications

1999

Vernon A, Burman W, Benator D, Khan A, Bozeman L for the Tuberculosis Trials Consortium. Acquired rifamycin mono-resistance among patients with HIV-related tuberculosis treated with supervised once weekly rifapentine and isoniazid. Lancet 1999; 353:1843-47.

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Burman W, Breese P, Weis S, Bock N, Bernardo J, Vernon A, TBTC. The effects of local review on informed consent documents from a multicenter clinical trials consortium. Clinical Trials 2003;24:245-55.

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2006

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Burman W, Benator D, Vernon A, Khan A, Jones B, Silva C, Lahart C, Weis SE, King B, Mangura B, Weiner M, El-Sadr W, and the Tuberculosis Trials Consortium. Acquired Rifamycin Resistance with Twice-Weekly Treatment of HIV-related Tuberculosis. *Am J Respir Crit Care Med* 2006;173: 350-356.

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[Authors]. Rifapentine Pharmacokinetics and Tolerability in Children and Adults Treated Once Weekly with Rifapentine and Isoniazid for Latent Tuberculosis Infection. *Journal of the Pediatric Infectious Diseases Society*, in press.

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II. Presentations and Abstracts

1997

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2000

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M Weiner, A Khan, A Vernon, B Burman, B Jones for the Tuberculosis Trials Consortium. Epidemiologic and clinical factors associated with the endpoint of *M. tuberculosis* culture-positivity in sputa after two-months of therapy for pulmonary tuberculosis. Poster presentation, IUATLD World Conference on Lung Health, Montreal CANADA, October 2002. *Int J Tuberc Lung Dis* 2002;6(Suppl 1):S189.

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Sterling TR, Hackman J, Horsburgh CR, Chaisson RE, Wang YC, Quinn E, Hamilton CD, Gordin F, Khan A, Donovan C, Menzies RI, McSherry G, Villarino ME and the TB Trials Consortium. Design of Tuberculosis Trials Consortium Study 26: Once-weekly rifapentine (RPT) + isoniazid (INH) for 3 months vs. daily INH for 9 months for the treatment of latent TB infection. 4th World Congress on Tuberculosis. Washington, DC. June 3-5, 2002. Abstract # 143.

2003

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Baertlein L, Moro RN, Borisov A, Goldberg S. Assessment of Severity Grading Differences Between Terms in Common Toxicity Criteria Used in Clinical Trials. Poster presentation: Drug Information Association's (DIA) Annual Meeting, Boston, MA, June 2013.

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Dorman S. Determining The Optimal Dose Of Rifapentine For Treatment Of Tuberculosis: How High Is High? Oral presentation: American Thoracic Society, Philadelphia, PA, May 20, 2013.

Ho C and Borisov A. Weekly INH/Rifapentine for LTBI: Initial Experiences and Future Prospects. Oral presentation: National TB Controllers Association Conference, Atlanta, GA, June 2013.

Kolwijck E, Friedrich SO, Venter A, van Ingen J, Diacon AH. Effect of culture supernatant containing resuscitation-promoting factors on the growth of M. tuberculosis from sputum samples collected during antituberculosis treatment. European Society for Clinical Microbiology and Infectious Diseases, April 27-30, 2013, Berlin, Germany.

Moro RN, Dorman S, Schluger NW, Stout J, Muzanyi G, Phan H, Feng, P-I, Heilig C, Bozeman L, Goldberg SV, Tolerability And Safety Of Escalating Rifapentine (RPT) Doses During The First 2 Months Of Tuberculosis (TB) Treatment. Poster presentation: American Thoracic Society, May 20, 2013, Philadelphia, PA, Am J Respir Crit Care Med 187;2013:A6051.

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Moro R. Safety of Once-weekly INH/Rifapentine- Update on Data from TBTC Study 26. Oral presentation: National TB Controllers Association Conference, Atlanta, GA, June 10, 2013.

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Schluger NW and Dorman S. Effect Of Sequester On CDC Tuberculosis Research. Oral presentation: American Thoracic Society, Philadelphia, PA, May 20, 2013.

Sterling TR. Toxicity, Tolerability and Completion of The New Rifapentine-Based Weekly Treatment For LTBI. Oral presentation: American Thoracic Society, Philadelphia, PA, May 20, 2013.

Villarino ME, Moro R, Borisov A, Adkinson NF, Phillips E, Shepherd G, Ho C, Weis SE, Sterling TR, and the Tuberculosis Trials Consortium. The rate and risk factors for drug hypersensitivity reactions among persons receiving 3 months of once-weekly rifapentine plus isoniazid for the treatment of latent tuberculosis infection (LTBI). Conference on Retroviruses and Opportunistic Infections, March 2013, Atlanta, GA.

Weiner M and MacKenzie W. Substudy to characterize rifapentine pharmacokinetic (PK) parameters in patients with TB. Pharmacokinetics and pharmacodynamics of rifapentine and rifampin. 6th International Workshop on Clinical Pharmacology of TB Drugs, Sept 2013

Weiner M and MacKenzie W. Substudy to characterize rifapentine pharmacokinetic (PK) parameters in patients with TB. Pharmacokinetics and pharmacodynamics of rifapentine and rifampin. Gates sponsored TB Modeling and Analysis Consortium meeting in Beijing, China

Weiner M and MacKenzie W. Substudy to characterize rifapentine pharmacokinetic (PK) parameters in patients with TB. Pharmacokinetics and pharmacodynamics of rifapentine and rifampin. CPTR meeting in Washington, DC - October, 2013

Dorman S and Goldberg S. Study 29X, Phase 2 clinical trial, is to compare tolerability and safety of arms containing escalating doses of rifapentine Presentation, INTER-TB, St. George's University, 25 October 2013

Dorman S and Goldberg S. Study 29X, Phase 2 clinical trial, is to compare tolerability and safety of arms

containing escalating doses of rifapentine Presentation, International Union Against Tuberculosis and Lung Disease, November 2013

III. Manuscripts and Presentations/Abstracts submitted or in preparation

A. Manuscripts

Bliven-Sizemore EE, Johnson JL, Goldberg S, Borisov A, Burman WJ, Dorman SE, Chaisson RE, Saukkonen JJ, and the Tuberculosis Trials Consortium. Hepatotoxicity in two phase 2 international multi-center trials of treatment for tuberculosis disease. Submitted.

Savic R, Lu Y, Bliven-Sizemore E, Weiner M, Nuermberger E, Burman W, Dorman SE, Dooley KE. Population pharmacokinetics of rifapentine and desacetyl rifapentine in healthy volunteers: nonlinearities in clearance and bioavailability. Manuscript submitted to AAC April 2013.

Heilig CM, Feng PJ, Joloba ML, Johnson JL, Morgan K, Gitta P, Boom WH, Mayanja Kizza H, Eisenach KD, Bozeman L, Goldberg SV. How we determined the most reliable solid medium for studying treatment of tuberculosis. 2013, submitted.

Joloba ML, Johnson JL, Feng PJ, Bozeman L, Goldberg SV, Morgan K, Gitta P, Boom WH, Heilig CM, Mayanja-Kizza H, Eisenach KD. What is the most reliable solid culture medium for tuberculosis treatment trials? 2013, submitted.

DeLuca A, Lessem E, Kanouse J, Wegener D, Mingote LR, Frick M. Activism on rifapentine pricing: removing cost barriers to improve uptake of TB research innovations. 2014, submitted to Lancet Respiratory Medicine

Chapman KN, Pevzner E, Breese P, Lamunu D, Mangan J, Shrestha-Kuwahara R, Nakibali JG, Goldberg S. Pilot evaluation of the informed consent process of CDC's Tuberculosis Trials Consortium. 2014, submitted.

Sterling TR, Moro R, Borisov AS, Phillips E, Shepherd G, Adkinson NF, Weis S, Ho C, Villarino ME, and the Tuberculosis Trials Consortium. Flu-like and other systemic drug reactions among persons receiving 3 months of weekly rifapentine plus isoniazid for treatment of latent tuberculosis infection. In preparation.

Shepherdson D, Mac Kenzie WR. Update on cost-effectiveness of a 12-dose regimen for latent tuberculosis infection at new rifapentine prices. In preparation.

B. Presentations and Abstracts

Reddy D, Minter M, Moro R, Feng P, Goldberg S, Saukkonen J, TBTC. Time-based analysis for alanine transaminase monitoring to detect hepatotoxicity during tuberculosis treatment. American Thoracic Society International Meeting, 2014.

Sterling T and Goldberg S. Three Months of Weekly Rifapentine + INH for M. tuberculosis Infection in HIV-infected Persons. Abstract submitted to CROI 2014.