DESMOND TUTU TB CENTRE

15 June 2016

FRIEDA VERHEYE-DUA
DESMOND TUTU TB CENTRE
DEPARTMENT of PAEDIATRICS AND CHILD HEALTH
FACULTY OF MEDICINE AND HEALTH SCIENCES
STELLENBOSCH UNIVERSITY
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Lower Ground level

DESMOND TUTU TB CENTRE

ADMIN HUB
DATA CENTER
Stellenbosch University SUN Clinical trials Unit (CTU)
PI: Mark Cotton
CTU co-PIs: Anneke Hesseling, Andreas Diacon

SUN CTU vision
Safe, effective, practical family-centered and integrated prevention, treatment and cure for HIV, TB and co-morbidities in individuals of all races, ages and gender, continuously refined through quality research, innovation and implementation

CRS I: FAM-CRU
CRS PI: Mark Cotton
CRS Coordinator: Joan Coetzee (IMPAACT & ACTG)
IMPAACT Study Coordinator: Lindee Ganger
ACTG study Coordinator: Charlotte Lawn

Focus areas
Pediatric HIV, maternal HIV, perinatal HIV transmission, adult HIV treatment, hepatitis, cervical cancer

Network involvement
IMPAACT, ACTG

Sites
Tygerberg Hospital
Satellite sites
Michael Mapongwana clinic
Kraaifontein community clinic
Bishop Lavis community clinic
Elsiesrivier community clinic
Bloekombos community clinic

CRS II: TASK
CRS PI: Andreas Diacon
CRS coordinator: Jeannine du Bois

Focus areas
Adult TB treatment, prevention, biomarkers

Network involvement
ACTG

Sites
Brooklyn Chest Hospital
Delft community clinic
Wallacedene clinic
Mbweni

Satellite sites
Delft Community Health Centre
Mfuleni Community Health Centre
Scottsdene Clinic

CRS III: DTTC-SU
CRS PI: Anneke Hesseling
CRS coordinator: Frieda Verheye-Dua

Focus areas
Pediatric and maternal TB (treatment, diagnostic and vaccines)

Network involvement
IMPAACT

Sites
Brooklyn Chest Hospital
Tygerberg Hospital

Satellite sites (future e.g. community prevention site)
Site B, Khayelitsha
CRS LEADER - ANNEKE HESSELING

13 Clinicians / Sub-Investigators

CRS Coordinator/Regulatory

7 Study Coordinators/Project Managers

9 Study Nurses

9 Data Staff

3 Lab staff

12 Counselors (English/Afrikaans/Xhosa)

9 support staff

5 Drivers

Paediatric Team

69 staff
Brooklyn Chest Hospital – 21 Km
Khayelitsha – 20 Km
Khayelitsha Nolungile Clinic
Site C
Current IMPAACT Sites and TB Burden

**FIGURE 2.5**

Estimated TB incidence rates, 2012
Risk of TB Disease and Death: Highest in the Youngest

- W Cape: TB notification >1000/100,000
- Annual risk of TB infection up to 4% in high-burden settings like SA
- Children < 5 and HIV- infected are at highest risk

Marais et al. Int J Tuberc Lung Dis. 2004
14 October 2014 - Site approval as IMPAACT Site 31790

P1101
Phase I/II Dose-Finding, Safety, Tolerance and Pharmacokinetics Study of a Raltegravir-Containing Antiretroviral Therapy (ART) Regimen in HIV-Infected and TB Co-Infected Children ≥ 2 Years to < 12 Years of Age (Version 2.0 dated 19 June 2015)
  Activation Protocol version 1.0 but study paused on 06 Feb 2015
  **Activation Protocol version 2.0 on 17 February 2016**
  First PID Screened 13 June 2016 – enrollment 21 June 2016

P1078
A phase IV randomised double blind placebo-controlled trial to evaluate the safety of immediate (antepartum-initiated) versus deferred (postpartum-initiated) IPT in HIV-infected women in high TB incidence settings.
  **Activation protocol version 1.0 on 22 June 2015**
  Enrolled 12 PIDs

Phoenix feasibility study A5300
Study of MDR TB Cases and Their Household Contacts: Operational Feasibility to Inform PHOENIx Trial Design
  **Activation protocol 13 November 2015**
  Enrolled 14 Index +53 Household cases
**Planned IMPAACT studies in near future:**

**P1026s**
Pharmacokinetic properties of antiretroviral and related drugs during pregnancy and postpartum

**P1108**
A Phase I/II, Open-Label, Single Arm Study to Evaluate the Pharmacokinetics, Safety and Tolerability of Bedaquiline (BDQ) in Combination with Optimized Individualized Multidrug-Resistant Tuberculosis (MDR-TB) Therapy in HIV-Infected and HIV-Uninfected Infants, Children and Adolescents with MDR-TB Disease.
Multi-Drug Resistant TB (MDR TB)

- 500,000 new cases of MDR-TB in 2011
- 50,000 paediatric cases; 400,000 infections
- Data and formulations for treatment of MDR and XDR TB in children are lacking
- MDR TB PK studies (observational), more than 300 kids in the past 4 year
- P1108 and P2005

WHO Global TB Report 2015
TB-CHAMP

A phase III cluster randomised placebo-controlled trial to assess the efficacy of preventive therapy in child contacts of multidrug-resistant (MDR) tuberculosis (TB)

- 814 households of adult MDR-TB source case (with on average 2 children per household)
- 192 weeks in total including enrolment over 72 weeks and follow-up for 96 weeks
DTTC MISSION
TO HAVE A TB FREE WORLD FOR THE NEXT GENERATION
“We call on the international community, which was so tremendous in its fight against another epidemic, apartheid, to show the same commitment to deal with TB and HIV/AIDS”