

Pre-screening protocol to identify HIV and TB infection and reduce costs of screening healthy adults for first in human TB vaccine trials in Gauteng, South Africa

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Background: South Africa has a high burden of HIV, DS-TB and MDR/RR-TB. First in human TB vaccine trials for the prevention of TB disease requires participation of healthy adults without evidence of HIV and TB infection and disease. We conducted pre-screening activities to identify HIV and TB infection prior to scheduling study-specific screening visits with the aim to establish a pipeline of potential participants and to reduce screening costs overall.

Methods: An ethics approved pre-screening protocol was implemented at the Aurum Pretoria Clinical Research Centre to assess participant eligibility to participate in HIV, TB and COVID clinical trials. Following informed consent, a questionnaire was administered to assess literacy, past and current health status, and willingness to participate in a vaccine study. For willing and potentially eligible participants, rapid HIV and IGRA testing was performed. Cost estimates included reimbursement and refreshments, supplies and consumables, and laboratory and radiology assessments.

Results: Between December 2023 and May 2024, 131 participants aged 17- 49 were pre-screened. 58% (76/131) of participants were female with 72.4% (55/76) on contraception. No previous TB was reported with only one positive TB symptom identified on symptom screen. Most participants reported not being vaccinated against SARS.CoV.2, 55% (72/131). The prevalence of HIV and TB infection was 4.9% (6/123) and 27.4% (29/106) respectively. 41.2% (54/131) of participants failed pre-screening, 64.8% (35/54) of whom were confirmed affected by HIV or TB infection. Pre-screening activities realized a saving of 68% of projected screening costs.

(Figure 1. A. Baseline Characteristics, B. Consort Diagram, C. Cost Estimates)

Discussion and Conclusion: An ethics approved pre-screening protocol has established a stable and cost-effective pipeline of willing and potentially eligible participants not affected by HIV or TB infection.

Funding Sources

Bill and Melinda Gates Foundation

Conflicts of Interest

None



A. Baseline Demographics and Clinical Characteristics

| Variable | N (%) |
|-----------------------------------------|-----------------|
| Pre-screened | 131 |
| Age in years | |
| Mean age (SD) | 26.5 (6.9) |
| Median Age (IQR) | 25 (21-31) |
| Range (min-max) | 17-49 |
| Sex | |
| Female | 76/131 (58.0%) |
| Contraception Use (Women of CBP) | |
| Yes | 55/76 (72.4%) |
| Previous TB | |
| No | 131 (100%) |
| TB symptom screen | |
| >/= 1 symptom | 1/131 (0.8%) |
| None | 130/131 (99.2%) |
| Prior COVID vaccination | |
| Yes | 59/131 (45%) |
| No | 72/131 (55%) |
| HIV Status | |
| Negative | 117/123 (95.1%) |
| Positive | 6/123 (4.9%) |
| IGRA Status | |
| Negative | 77/106 (72.6%) |
| Positive | 29/106 (27.4%) |

C. Cost Estimates

| | |
|------------------------|--------------|
| Cost of 54 screenings | R 282 286,04 |
| Cost of 54 pre-screens | R 91 112,36 |
| Saving | R 191 173,68 |
| % of total | 68% |

