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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 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

Participants

- 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).

Prevalence

- The prevalence of HIV and TB infection was 4.9% (6/123) and 27.4% (29/106) respectively.
- Baseline Demographics and Clinical Characteristics of the pre-screened participants are shown in Figure A.

Baseline Demographics and Clinical Characteristics of pre-screened healthy adults in Gauteng, South Africa, 2023-2024

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	123/131 (93.9%)
Negative	117/123 (95.1%)
Positive	6/123 (4.9%)
IGRA Status	106/117 (90.6%)
Negative	77/106 (72.6%)
Positive	29/106 (27.4%)

Figure A

Pre-screen protocol saves 68% of projected screening costs for FIH TB vaccine trial

Pre-screen Failures

- 41.2% (54/131) of participants failed pre-screening, 64.8% (35/54) of whom were confirmed affected by HIV or TB infection.
- The consort flow for participants recruited is shown in Figure B.

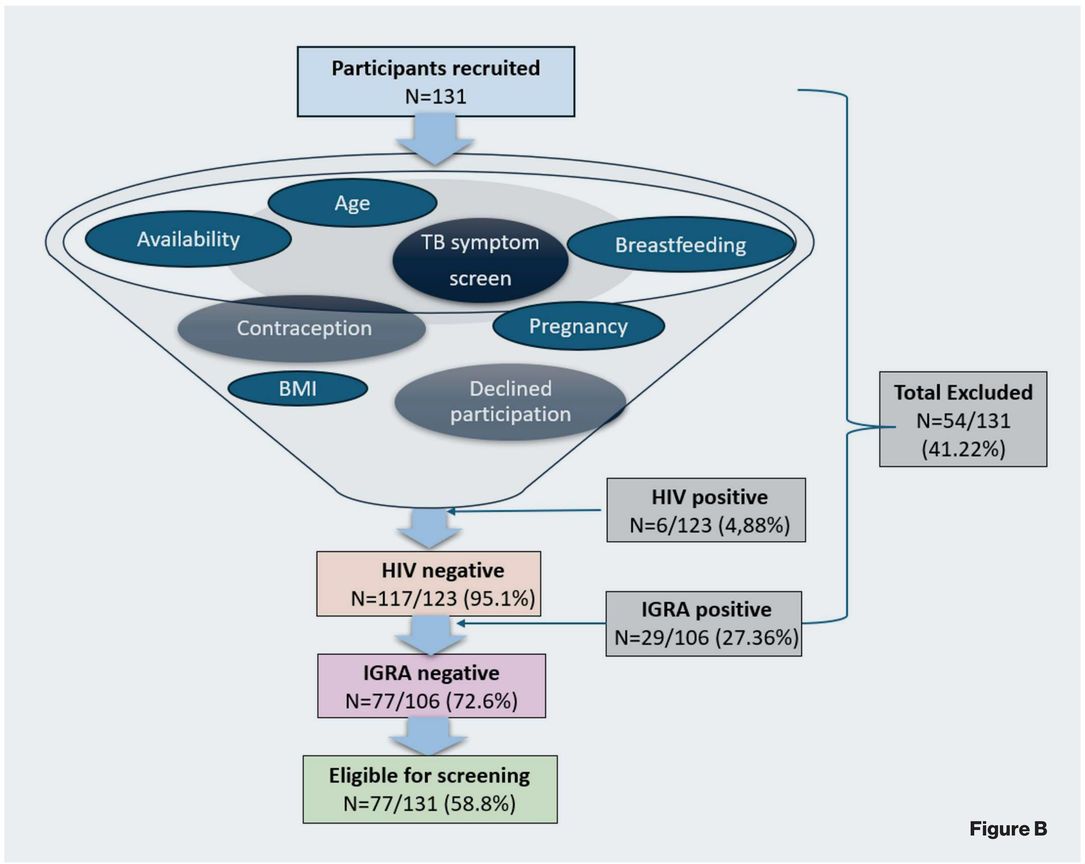

Figure B

Cost Estimates

- Pre-screening activities realized a saving of 68% of projected screening costs for 54 participants who failed pre-screening, , shown in Figure C.

Cost Estimates Per Participant	Pre-screen Costs	Screening Costs
Reimbursement	$4,19	$27,54
Refreshments	$4,96	$9,92
Clinic and Office supplies	$0,07	$21,80
Laboratory tests	$87.40	$192.46
Radiology tests	$0	$56,89
Point of care tests	$4,41	$4,41
Total cost	**$101,03**	**$313,03**
Calculation of Savings*		
Cost of 54 screenings	$16 903,36	
Cost of 54 prescreens	$5 455,83	
Saving	$11 447,56	
Saving (% of total screening cost)	**68%**	
*Foreign exchange rate: 1US$=ZAR16.70		

Figure C

Discussion/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 for phase 1a FIH TB vaccine trials with strict eligibility criteria and small sample sizes.
- This saving may not be applicable to phase 2/3 trials.

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