

Planned, ongoing and completed tuberculosis treatment trials in Brazil, Russia, India, China and South Africa: a cross-sectional descriptive analysis.

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Background: Tuberculosis (TB) remains a deadly challenge globally and Brazil, Russia, India, China, and South Africa (BRICS) are amongst the countries with the highest TB burden. The objective of this study was to identify and describe ongoing, planned, and completed TB trials conducted in the BRICS countries registered in World Health Organisation International Clinical Trial Registry platform (WHO-ICTRP); to evaluate the time to publication and to report selective outcome reporting by comparing primary outcome in published trials with their pre-specified outcomes in registry records.

Methods and analysis: We searched the WHO - ICTRP portal (20 January 2019) and the Russian Federation Registry (30 March 2019) to identify TB trials conducted in BRICS countries. Two researchers independently screened and extracted data into Excel. Descriptive analysis, comparative analysis and time to publication was conducted using STATA software.

Results: The search of the WHO-ICTRP yielded 408 trials and an additional 32 trials were

identified from the Russian registry. Of those, 253 were included in the analysis. We found that 77 trials are multi -countries trials, followed by trials in China (55), India (53), South Africa (34), Russia (23), and Brazil (11). One hundred and sixty-two trials were registered prospectively and 70 retrospectively. Most trials (205) evaluated TB treatment, followed by 29 behaviour change interventions, 13 nutritional supplementation, four surgical interventions and two assessing rehabilitation. Thirty - one of the 101 published trials had evidence of selective outcome reporting. The time to publication was a median of 25 months (IQR 15-37) from the time of anticipated end date stated in the registry.

Conclusion: BRICS trial activity indicates that most trials are investigating interventions of drug treatment, with fewer addressing socio-behavioural issues affecting adherence to treatment. Selective outcome reporting was low in the publications, however, should be further minimised to enhance the credibility and transparency in published TB trials.