

## Publication

## Ultrasound in managing extrapulmonary tuberculosis: a randomised, controlled, parallel, superiority, open-label trial

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BACKGROUND: Patients with suspected extrapulmonary tuberculosis are often treated empirically. We hypothesized that extended Focused Assessment of Sonography for HIV and Tuberculosis (eFASH), in combination with other tests, would increase the proportion of correctly managed patients with suspected extrapulmonary tuberculosis. METHODS: This trial in adults with suspected extrapulmonary tuberculosis was performed in a rural and an urban hospital in Tanzania. Participants were randomised 1:1 to intervention or routine care, stratified by site and HIV status. All participants received a clinical evaluation, chest X-ray, sputum Xpert MTB/RIF, and urine Xpert MTB/RIF Ultra. The intervention was a management algorithm based on eFASH plus microbiology, adenosine deaminase (ADA) and chest X-ray. The primary outcome was the proportion of correctly managed patients. Presence of positive microbiology or ADA defined definite tuberculosis. An independent endpoint review committee determined diagnoses of probable or no tuberculosis. We evaluated outcomes using logistic regression models, adjusted for randomisation stratification factors. RESULTS: From 09/2018 to 10/2020, 1,036 patients were screened and 701 randomised (350 intervention, 351 control). 251 (72%) intervention participants had a positive eFASH. 258 (74%) intervention and 227 (65%) control participants were initiated anti-tuberculosis treatment at baseline. More intervention participants had definite tuberculosis (n = 124, 35%) compared to controls (n = 85, 24%). There was no difference between groups for the primary outcome (intervention 266/286 (93%); control: 245/266 (92%); odds ratio 1.14 (95% confidence interval 0.60-2.16, p = 0.68)). There were no procedure-associated adverse events. CONCLUSION: eFASH did not change the proportion of correctly managed patients, but increased the proportion of definite tuberculosis.

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