

Optimal mid-upper arm circumference-based discharge criteria for community-based-management of severe acute malnutrition in India: a randomized controlled non-inferiority trial

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Introduction

Most interventions for community-based management of severe acute malnutrition (CM-SAM) worldwide utilise mid-upper arm circumference (MUAC) <115mm for eligibility and ≥125mm for discharge. However, this discharge criterion is based on very limited evidence, with no data from the Indian subcontinent. India, home to over one-third of malnourished children globally, provides facility-based care based on weight-for-height with no guidelines for CM-SAM. Previous observational data suggests relapse in children reaching ≥120mm is similar to that for ≥125mm, whilst duration of treatment required to achieve ≥125mm is nearly doubled, with higher default rates. This trial in the state of Jharkhand, India investigated whether discharge with MUAC ≥120mm is non-inferior to MUAC ≥125mm for risk of relapse to SAM or death.

Methods

We conducted a multicentre randomized controlled non-inferiority trial for SAM children aged between six and 59 months across 46 centres in Jharkhand, India. Over 12 months, children with MUAC<115mm and without oedema at admission were randomly allocated to be discharged either at MUAC ≥120 mm or MUAC ≥125mm. Endpoints were status at three months (primary) and six months (secondary) after reaching their allocated discharge MUAC. Non-inferiority was concluded if the upper bound (UB) of a one-sided 95% confidence interval was within a pre-defined 13% margin, based on pragmatic operational indicators.

Ethics

This study was approved by the MSF Ethics Review Board and by the Ethical Review Boards of the Rajendra Institute of Medical Sciences, Ranchi and Jawaharlal Nehru University, New Delhi, India, and London School of Hygiene & Tropical Medicine, UK. Clinical Trials Registry – India number, CTRI/2017/12/010743.

Results

Of 633 children enrolled, 316 were allocated to the standard of care arm (discharge at ≥125mm) and 317 to the ≥120mm arm. No significant clinical-epidemiological differences were detected between cohorts not reaching their allocated discharge MUAC, however there was a higher proportion of treatment non-response (17.5% vs 9%) in the 125mm arm. Of 194 and 236 children reaching discharge criteria in each arm respectively, 176 and 216 were eligible for intention-to-treat analysis. For the standard of care arm, 42% of children were male, with a mean age of 12.6 months (standard deviation, SD; 7.9); for the ≥120mm arm, 41% were male, with a mean age of 12.1 months (SD; 7.1). Overall, non-inferiority was observed within three months; unadjusted risk difference (RD) 6.4%, 95% UB=11.6%, ≥125mm: n=14 (8.0%; 14 relapse, 0 death), ≥120mm: n=31 (14.4%; 30 relapse, 1 death). In pre-specified stratified analyses, non-inferiority was observed in children with MUAC 110-114mm at enrolment (N=285, RD 2.0%, 95% UB 7.5%); however, inferiority was observed with MUAC<110mm (N=107, RD 17.5%, 95% UB 29.0%). In stratified secondary outcome analyses at six months, conclusions were similar.

Conclusion

Using a non-inferiority margin of 13%, results support ≥120mm as a discharge criterion in children admitted with MUAC 110-114mm, but not in those with MUAC<110mm. This margin in children discharged earlier needs to be balanced against greater capacity for programmatic coverage. Considering over two-thirds of children are admitted with MUAC 110-114mm, defining discharge criteria by admission MUAC may have important implications on increasing capacity and cost-effectiveness of CM-SAM programming in India.

Conflicts of interest

None declared.



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Elisa Marion is a Public Health Nutritionist, specialising in the field of emergency nutrition and child undernutrition. She held several positions with MSF and other organisations focusing on the management and implementation of programmes, surveys and operational research studies in the field of nutrition. In her last role she was the nutrition advisor for MSF OCG. Ms Marino holds a MPH in nutrition from the London School of Hygiene and Tropical Medicine and a BA in Dietetics and Human Nutrition from McGill University, Montreal.