Optimising malnutrition treatment in children 6-59 months: primary outcome of a randomized trial, Democratic Republic of Congo

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Introduction

The Optimising MAlnutrition treatment (OptiMA) strategy aims to simplify current malnutrition treatment protocols for children with mid-upper arm circumference (MUAC)<125mm or oedema, by supplementing with one product—ready-to-use therapeutic food (RUTF), using gradually reducing doses as a child's weight and MUAC increases.

Methods

This non-inferiority, randomized controlled trial was conducted in Kasai province, Democratic Republic of Congo (DRC). It compared the OptiMA strategy with the effective standard DRC protocol, using increasing weight doses of RUTF for treating severe acute malnutrition (SAM) and ready to use supplementary food (RUSF) at fixed dose for moderate acute malnutrition. Children aged 6–59 months with MUAC<125mm or weight-for-height Z score<–3 or oedema, and without medical complications, were randomized to either OptiMA or the standard protocol, and followed up for six months. Primary outcome was a composite indicator at 6 months' follow-up: child alive, not acutely malnourished per the study definition, and without any additional episode of acute malnutrition throughout the observation period. Non-inferiority was determined if the upper boundary of the 95% confidence interval (CI) for the difference between randomized arms in the proportion of children with favourable outcome was less than 10%, for both intention-to-treat (ITT) and per-protocol (PP) analyses. Superiority was determined if the upper boundary of the 95% CI for this difference was lower than 0%.

Ethics

This study was approved by the National Congolese Health Ethics Committee and by the Ethics Evaluation Committee of Inserm, the French National Institute for Health and Medical Research. ClinicalTrials.gov number, NCT03751475.

Results

Between July 2019 and July 2020, 981 children were enrolled. 896 children were included in ITT analysis, with 450 in the OptiMA arm and 446 standard; 792 were included in PP analysis. Over the entire follow-up, 450 (100%) children under OptiMA received RUTF treatment while under the standard protocol, 315 (71%) received RUTF or RUSF or both. ITT analysis found that 325 (72.2%) children had favourable outcome under OptiMA versus 282 (63.2%) in the standard arm (difference: -9.2%, 95%CI -15.9% to -2.0%). Under OptiMA, weight gain was greater (median weight gain, 1700g versus 1600g, p= 0.003), the nutritional treatment consumption lower (median of 64 of RUTF versus 102 sachets of RUTF/RUSF under standard; p= 0.018). Median time to recovery (ie, MUAC>124mm without oedema for two consecutive visits) was lower under OptiMA than under standard: 5 weeks (95%CI 5–5) versus 9 weeks (95%CI 8–10), p<0.001. We did not observe a difference in hospitalization rates (10% OptiMA, 7% standard, p=0.228) or mortality rates (0.2% in both arms).

Conclusion

OptiMA led to better anthropometric status over a six-month period and expanded access to treatment, whilst the standard protocol partially addressed global acute malnutrition with higher consumption of nutritional products used in the trial. Our findings suggest it may be beneficial to address global acute malnutrition in one program using one product at a gradually adjusted dose.

Conflicts of interest

None declared.

Cécile Cazes

Cécile Cazes is the scientific project leader of the OptiMA-DRC trial, based at the University of Bordeaux, France. She joined the Clinical & Operational Research Alliance, a partnership between the Alliance for International Medical Action and INSERM, France's national medical research institute, three years ago. She is currently conducting a PhD on OptiMA, a simplified and optimized approach for treatment of malnutrition in children. Previously, Cécile worked as a project coordinator and medical coordinator with MSF and other non-governmental organizations, mainly in West and Central African settings, and as nurse in French Guyana.