Optimising acute malnutrition treatment is non-inferior to standard protocol in uncomplicated severely wasted children: main secondary outcome of a randomised controlled trial in Democratic Republic of Congo.

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Introduction

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

Objective

To determine whether the recovery rate of children with uncomplicated severe acute malnutrition (SAM) according to the current WHO definition (ie, MUAC <115 mm or weight-for-height Z-score, WHZ, <-3 or bilateral oedema) managed under the OptiMA protocol is non-inferior to that of the national standard protocol during trial follow-up.

Methods

- Non-inferiority individually randomised controlled trial
- Nested in a post-conflict emergency program in Kasai province
- 4 health centres, 60 villages, one district hospital included
- Children aged 6–59 months with MUAC <115 mm OR WHZ <-3 OR bilateral oedema (+, ++) without medical complications
- 6 months follow-up post-inclusion, follow-up visits in the village twice a month after discharge from health centre or in case of absence during outpatient weekly visits

Ethics

Approved by the National Health Ethics Committee, MoH, and the Ethics Evaluation Committee of Inserm, the French National Institute for Health and Medical Research (Paris, France).

Results

Main secondary outcome

Recovery over the trial follow-up
- 4 week minimum duration of RUTF treatment and
- Temperature <37.5°C and
- Absence of bilateral oedema and
- MUAC >124 mm
- For OptiMA arm: MUAC > 124 mm or WHZ ≥1.5

Main analysis
- Non-inferiority analysis comparing both arms on an intention-to-treat (ITT) and per-protocol (PP) basis

Secondary outcomes
- Anthropometric changes, quantity and length of RUTF treatment among the children who recovered
- Recovery rate and time to recover with the same recovery definition applied in both arms (standard definition, OptiMA definition)

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>Standard</th>
<th>OptiMA</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (months), median</td>
<td>17 (IQR 10–30)</td>
<td>16 (IQR 9–29)</td>
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<tr>
<td>MUAC (mm)</td>
<td>114 (IQR 110–121)</td>
<td>114 (IQR 111–120)</td>
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<tr>
<td>Nutritional oedema</td>
<td>49 (20%)</td>
<td>38 (16%)</td>
<td></td>
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<tr>
<td>WHZ&lt;-3</td>
<td>-3.8 (1.0)</td>
<td>-3.5 (1.0)</td>
<td></td>
</tr>
<tr>
<td>HAZ&lt;-3</td>
<td>-3.0 (1.7)</td>
<td>-2.9 (1.7)</td>
<td></td>
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<tr>
<td>Malaria confirmed and treated</td>
<td>116 (48%)</td>
<td>114 (47%)</td>
<td></td>
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<tr>
<td>Diarrhoea</td>
<td>7.3 (3%)</td>
<td>7.3 (3%)</td>
<td></td>
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<tr>
<td>Aminosorcin received</td>
<td>240 (100%)</td>
<td>242 (100%)</td>
<td></td>
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</tbody>
</table>

Follow-up characteristics

Complete 6 months follow-up
- 232 (96.7%) | 228 (94.2%)
- Hospitalization or loss to follow-up
- Death
- Outpatient visits, mean (SD)
- Home follow-up visits, mean (SD)
- At least one hospitalisation

Data are n (%) or median [IQR] (mean [standard deviation]) MUAC = mid-upper arm circumference; WHZ = weight-for-height z-score; HAZ = height-for-age z-score; β: the calculation excludes children with nutritional oedema.

Conclusion

Progressive RUTF dose reduction in children with SAM according to OptiMA strategy is not inferior to standard DRC RUTF dosage. Children under the OptiMA protocol who recovered presented better MUAC status, total weight and MUAC gain at the recovery visit, compared to their peers under standard DRC protocol. These findings could have substantial individual and public health implications.

Acknowledgements

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