

GASTROSAM: Exploring the best rehydration strategies for malnourished children with moderate to severe dehydration

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Context

Children hospitalised with severe acute malnutrition (SAM) often present with gastroenteritis and dehydration. The current WHO guidelines restrict intravenous rehydration (IV) in this group due to safety concerns as they are perceived to be at risk of heart failure. For oral rehydration in children with SAM it is recommended to use Resomal instead of standard ORS. However, these recommendations are based on weak evidence.

Methods

A randomised controlled open-label factorial trial in 6 sites in Uganda, Kenya, Niger and Nigeria enrolled 415 children in 2 strata - severe and moderate dehydration - between 2019 and 2024. Children with severe dehydration (n=272) were randomised (2:1:1) to the control group (standard of care) or to one of two liberal IV strategies. All children were randomised (1:1) to receive Resomal or standard ORS. Children were followed up to 28 days. The primary outcome of the severe dehydration comparison was mortality at 96 hours, and for the oral rehydration comparison it was change in sodium at 24 hours.

Results

In the severely dehydrated children, there was no difference in mortality at 96 hours between the liberal and control groups (risk ratio 1.02 (0.41,2.52); p=0.69). Overall mortality at 96 hours was lower than anticipated (7%). No suspected pulmonary oedema or secondary heart failure events were reported in the trial, and there was no evidence of a difference in serious adverse events.

In the ORS comparison, the change in sodium at 24 hours was similar between standard ORS vs Resomal (mean difference -0.6 (-1.9, 0.7) mmol/L).

Conclusion

While there was no evidence for a difference in mortality, there was no evidence of harm with giving IV fluids for rehydration nor with using standard ORS instead of Resomal for children with SAM. The trial is an important addition to a limited body of evidence.

Investigating whether IV rehydration for severely malnourished children with dehydration is beneficial and whether standard ORS can be given safely to malnourished children with dehydration.