STUDY FACTS

Rapid enteric testing to permit targeted antimicrobial therapy, with and without *Lactobacillus reuteri* probiotics, for paediatric acute diarrhoeal disease in Botswana: A pilot, randomized, factorial, controlled trial

Principal investigator
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Study objective
To verify the feasibility of a randomized controlled trial designed to measure the benefit of rapid enteric diagnostic testing and *Lactobacillus reuteri* DSM 17938 (*L. reuteri* Protectis) therapy for children admitted to hospital in Botswana with acute diarrhea.

Study design
A placebo-controlled, randomized trial in 71 infants 2-60 months (median age 10.8 months). All infants received standard fluid rehydration plus zinc and were randomized to one of the following treatments:

1) Rapid diagnostic testing (plus targeted antimicrobial therapy if indicated) plus 5 drops daily of *L. reuteri* Protectis for 60 days
2) Rapid diagnostic testing (plus targeted antimicrobial therapy if indicated) plus 5 drops daily of placebo for 60 days
3) Standard care (no diagnostic testing) plus *L. reuteri* Protectis for 60 days
4) Standard care (no diagnostic testing) plus placebo for 60 days

Outcome parameters
Primary outcome was achievement of feasibility including validation of protocols, ensuring that testing and treatment could be integrated into clinical care, and verifying recruitment rates. The primary clinical outcome was height-for-age (HAZ) at 60 days adjusted for baseline HAZ. Secondary clinical outcomes included recurrence of diarrhea in the 60-day follow-up period and nine other outcome parameters.

Results
Rapid diagnostics in combination with supplementation of *L. reuteri* Protectis for 60 days showed a significant increase in 60-day adjusted height-for-age and significantly less recurrent diarrhea compared to standard care plus placebo therapy. Rapid testing plus placebo therapy did not show any significant differences compared to standard care and placebo.

A significant effect on less recurrent diarrhea was shown also for *L. reuteri* Protectis per se, in the group that received standard care plus *L. reuteri* Protectis for 60 days. The changes in length were non-significant, however.