

# Rifaximin 200 mg Plus Oral Rehydration vs Oral Rehydration Alone in Children With Acute Diarrhea

NCT07285785

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Status	RECRUITING
Phase	Phase 4
Sponsor	Bausch Health Americas, Inc.
Enrollment	54 participants

## Key Eligibility Criteria

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### Inclusion (9)

- Consent and assent are appropriately obtained prior to any study related activities, including discontinuation of any prohibited medications (subjects must sign an assent for the study and a parent or a legal guardian must sign the informed consent).
- Subject is between 6 to 11 (and 11 months) years of age, inclusive, and weighs at least 15 kg (33 lbs) at Screening.
- Females of childbearing (reproductive) potential must have a negative urine and serum pregnancy test at Screening and agree to use a highly effective method of contraception throughout their participation in the study. Acceptable methods of contraception are those alone or in combination, that result in a low failure rate (ie, less than 1% per year) when used consistently and correctly and include hormonal methods (oral, injected or implanted), intrauterine device or intrauterine system or double barrier methods (simultaneous use of a physical barrier method by the subject and male partner, including a male condom and an occlusive cap [diaphragm or cervical/vault cap] with spermicidal). Abstinence or partner(s) with a vasectomy may be considered an acceptable method of contraception at the discretion of the Investigator.
- NOTE: Female subjects are considered of child-bearing potential if they are (a) physiologically capable of becoming pregnant, defined as a female who has experienced menarche and (b) they will be, or could possibly be, engaging in sexual activity during the course of the study.
- Subject has diarrhea of suspected bacterial etiology defined by:  
... and 4 more (see full listing online)

### Exclusion (23)

- Subject has a history of chronic diarrhea.
- Subject is unable to eat or drink.
- Subject has at least one of the following signs or symptoms:
  - Presence of fever  $>39^{\circ}\text{C}$  ( $>102.2^{\circ}\text{F}$ ).
  - Presence of frank blood in stool.
- ... and 18 more (see full listing online)

## Locations (5 total)

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Direct Helpers, Hialeah, Florida, United States  
SouthCoast Research Center, Miami, Florida, United States  
Oceane7 Medical & Research Center, Inc, Miami, Florida, United States  
... and 2 more locations

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<https://clinicaltrials.gov/study/NCT07285785>

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