

Single Dose Antibiotic Treatment of Acute Watery Diarrhea, Rifaximin Versus Azithromycin, With Loperamide Adjunct

NCT05677282

Status	RECRUITING
Phase	Phase 4
Sponsor	Henry M. Jackson Foundation for the Advancement of Military Medicine
Enrollment	150 participants

Key Eligibility Criteria

Inclusion (5)

- Active duty military, 18-60 years old
- Presence of acute watery diarrhea (3 or more loose/liquid stools in 24 hours or 2 loose/liquid stools in 24 hours and associated symptoms such as nausea, vomiting, abdominal cramps or tenesmus) lasting ≤ 96 hours in duration that impacts function in activities and/or performance of primary duties. Refer to recruitment decision tree below.
- Eligible for ambulatory management. (Note: Ambulatory management in this study means that the patient can be treated on an outpatient basis to include up to 23 hours of medical observation and IV therapies.)
- Able to comply with follow-up procedures.
- Will remain in country for at least 7 days or an assurance that follow-up can be arranged elsewhere.

Exclusion (9)

- Allergy to rifamycins, macrolides, or loperamide (not including mild gastrointestinal upset).
- Antibiotic therapy in the 72 hours prior to presentation (excluding malaria prophylaxis with mefloquine, malarone, chloroquine/proguanil, tafenoquine, or doxycycline).
- Concomitant medications with known drug-drug interactions with any of the study drugs (includes theophylline, digoxin, warfarin, chloroquine and hydroxychloroquine).
- Current or history of liver disease or other serious health conditions based on review by study physician.
- Acute dysentery and/or febrile illness (temperature $> 100.4^{\circ}\text{F}$ [38.1°C]).

... and 4 more (see full listing online)

Locations (4 total)

Camp Lemonnier Djibouti, Djibouti, Djibouti
JTF-Bravo, Soto Cano AB, Comayagua, Honduras
British Army Training Site UK, Nanyuki, Kenya
... and 1 more locations

<https://clinicaltrials.gov/study/NCT05677282>

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