

# Comparison of Three Interventions for Antibiotic-Resistant Bacteria (ARB) Decolonization From the Gastrointestinal Tract

NCT07094984

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Medical University of Warsaw
Enrollment	360 participants

## Key Eligibility Criteria

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### Inclusion (12)

- Age  $\geq$  18 years;
  - Documented intestinal colonization with antibiotic-resistant bacteria confirmed by at least two positive cultures (rectal swabs or, alternatively, stool cultures), with the last positive result obtained at least 28 days prior to the planned procedure;
  - Documented colonization by one or more of the following bacterial strains:
    - Carbapenem-resistant strains with confirmed resistance mechanisms, including MBL+ (NDM+, VIM+, or others), KPC+, OXA-48+, or phenotypic carbapenem resistance without identified genetic mechanism;
    - Multidrug-resistant Enterobacteriaceae resistant to beta-lactams and other antibiotics, especially ESBL-producing strains, including Escherichia, Enterobacter, Klebsiella spp., and/or P. aeruginosa, A. baumannii (commonly associated with the ESKAPE group);
- ... and 7 more (see full listing online)

### Exclusion (13)

- Lack of consent to participate in the study or inability to establish logical contact and obtain consent from an authorized representative;
  - Absolute neutrophil count (ANC)  $<$  500 cells/ $\mu$ L on the day of FMT (within 3 days prior) or predicted decline to this level within the next 2 days;
  - Diagnosed HIV infection with CD4 lymphocyte count  $<$  250 cells/ $\mu$ L;
  - Active infection requiring antibiotic therapy on the day of FMT or planned antibiotic use during the first 7 days following FMT;
  - Symptoms or radiological/endoscopic evidence of gastrointestinal mucosal damage within 7 days prior to FMT (e.g., ulceration, perforation, gastrointestinal bleeding) posing a risk of serious adverse events;
- ... and 8 more (see full listing online)

## Locations (1 total)

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Uniwersyteckie Centrum Kliniczne Warszawskiego Uniwersytetu Medycznego, Klinika Hematologii, Transplantologii i Chorób Wewn trznych, Warsaw, Poland

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<https://clinicaltrials.gov/study/NCT07094984>

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