KURZPROTOKOLL
FEMITRANS

Wissenschaftl. Titel	Fecal microbiota transfer for the secondary prevention of recurrent urinary tract infections in premenopausal women: a phase II
Kurztitel	FEMITRANS
Studienart	multizentrisch, prospektiv, MPG-Studie, Investigator Initiated Trial (IIT)
Studienphase	Phase II
Erkrankung	Infektionen: sonstige
Einschlusskriterien	- 1. Premenopausal adult women with recent history of rUTI defined as >= four UTI during the last 12 months. A UTI is defined as presence of at least one typical symptom (dysuria, alguria, pollakiuria or flank pain) in the absence of alternative causes - 2. Unsuccessful secondary prophylaxis of rUTI by lifestyle modifications including increased water intake and postcoital voiding - 4. Written informed consent obtained according to international guidelines and local laws - 5. Ability to understand the nature of the trial and the trial related procedures and to comply with them - 3. Last acute symptomatic UTI episode confirmed by urinary culture and caused by either Escherichia coli or Klebsiella pneumoniae susceptible to fosfomycin
Ausschlusskriterien	- 1. Inability to swallow 30 FMT capsules and undergo bowel lavage - 10. Known phenylketonuria or glucose-6-phosphate dehydrogenase deficiency - 11. Known allergy, hypersensitivity or intolerance to any of the used investigational medicinal products - 12. Planned or ongoing intake of prohibited concomitant medication as per protocol - 13. Currently enrolled in another interventional trial - 14. Failure to use one of the following safe methods of contraception: female condoms, diaphragm or coil, each used in combination with spermicides; intra-uterine device; hormonal contraception in combination with a mechanical method of contraception; e.g. Women can only take part in this study if the risk of becoming pregnant is absolutely minimized. Save contraceptive methods comprise: female condoms, diaphragm or coil, each used in combination with spermicides; intra-uterine device; hormonal contraception in combination with a mechanical method of contraception and have to be used while participating in the study; (see section 7.5.3) - 15. Other conditions that according to the investigator might interfere with the evaluation of study objectives or patient safety - 2. Known anatomical or functional abnormalities in the lower urinary tract including neurogenic bladder and incontinence - 3. Modifiable risk factors for rUTI (e.g. uncontrolled diabetes mellitus) - 4. Current pregnancy - 5. Uncontrolled inflammatory bowel disease (e.g. ulcerative colitis or Crohn's disease) defined as the necessity to start or modify immunosuppressive treatment within the preceding three months due to disease activity - 6. Presence of severe intestinal inflammation due to other cause - 7. Advanced stage chronic heart failure (NYHA III/IV) - 8. Gastrointestinal perforation, obstruction, ileus or retention of gastric contents

	- 9. Severe immunosuppression defined as at least one of the following: (a) patients with current or foreseeable neutropenia within the 14 days of study treatment (defined as <500 neutrophils/ml) (b) patients scheduled for or having received CAR-T -cell therapy or allogeneic stem cell transplantation (SCT) or solid organ transplantation within 100 days prior or after enrolment (c) patients with active graft versus host disease or allograft rejection requiring intensified immunosuppressive treatment (d) patients treated with corticosteroids equivalent to prednisone >=20 mg daily for 14 consecutive days prior or after enrollment (e) patients with HIV infection with CD4+ cell count <200/mm³ within the past 3 months of screening
Alter	18 - 64 Jahre
Sponsor	Goethe-Universität Frankfurt
Förderer	Else Kröner-Fresenius-Stiftung
Registrierung in anderen Studienregistern	EUCT 2025-520452-28-00
Links	Link