# *KURZPROTOKOLL*
# *SUMMIT*

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| **Öffentlicher Titel** | Phase III Studie zu Ridinilazole und Vancomycon bei einer Infektion mit Clostridium difficile |
| **Wissenschaftl. Titel** | A phase 3, randomized, double-blind, active controlled study to compare the efficacy and safety of ridinilazole (200mg bid) for 10 days with vancomycon (125mg qid) for 10 days in the treatment of Clostridium difficile infections (CDI) |
| **Kurztitel** | SUMMIT |
| **Studienart** | multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig |
| **Studienphase** | Phase III |
| **Erkrankung** | Infektionen: Bakterielle Infektionen |
| **Einschlusskriterien** | - Patient must be at least 18 years of age, at the time of signing the informed consent.<br>- Have signs and symptoms of CDI including diarrhea such that in the Investigator's opinion, CDI antimicrobial therapy is required. Diarrhea is defined as a change in bowel habits, with >=3 unformed bowel movements (UBMs) (5, 6 or 7 on the Bristol Stool Chart) in the 24 h prior to randomization.<br>- Have the presence of either toxin A and/or B of C. difficile in the stool determined by a positive free toxin test (using a Sponsor agreed test). The stool sample must be current (produced within 72 hours prior to randomization).<br>- Male or Female Male patients: - A male patient must agree to use contraception as detailed in Section 10.4 of this protocol during the treatment period and for at least 30 days after the last dose of study treatment and refrain from donating sperm during this period. Female patients: - A female patient is eligible to participate if she is not pregnant, not breastfeeding, and at least one of the following conditions applies: i. Not a woman of childbearing potential (WOCBP) OR ii. A WOCBP who agrees to follow the contraceptive guidance during the treatment period and for at least 30 days after the last dose of study treatment.<br>- Has provided documented signed informed consent and any authorizations required by local law (e.g. Protected Health Information [PHI]). If unable to read, understand and sign the informed consent form a legally authorized representative (LAR) may provide consent on the patient's behalf if permitted by the Institutional Review Board (IRB)/Ethics Committee (EC). |
| **Ausschlusskriterien** | - Have had more than one prior episode of CDI in the previous 3 months or more than 3 episodes in the past 12 months prior to randomization.<br>- Have a history of chronic diarrheal disease including inflammatory bowel disease (Crohn's disease or ulcerative colitis).<br>- Have had a positive diagnostic test for other GI pathogens, considered to be clinically relevant, within 2 weeks of randomization.<br>- Have had major gastrointestinal (GI) surgery (e.g. significant bowel resection) within 3 months of randomization (this does not include appendectomy). The presence of a colostomy or ileostomy or likely requirement of an ostomy during the study.<br>- Have life threatening or fulminant CDI with evidence of hypotension, septic shock, peritoneal signs or absence of bowel sounds, or toxic megacolon.<br>- History of bone marrow or hematopoietic stem cell transplant at any time or a known current history of a severely compromised/suppressed immune system that, in the opinion of the Investigator, would make the patient unsuitable for the study.<br>- Have had more than the equivalent of 24 hours of dosing of antimicrobial treatment active against the current episode of CDI prior to randomization. (i.e. more than four doses of oral vancomycin, two doses of fidaxomicin or three doses of metronidazole).<br>- Prior or current use of anti-toxin antibodies including bezlotoxumab within the past 6 months prior to randomization. |

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| | - Are unable to discontinue products used affecting disease progression at randomization.<br>- Has been involved in a clinical trial and received an investigational medicinal product for indications other than CDI within 1 month or five half-lives (whichever is longer) or within 3 months if the investigational medical product was for CDI.<br>- Have received an investigational vaccine against C. difficile.<br>- Patients that the Investigator feels are inappropriate for the study this would include those; with any other condition that, in the Investigator's judgment, would make the patient unsuitable for inclusion in the study. who, in the opinion of the Investigator, are not likely to complete the study for whatever reason, e.g. short life expectancy. with known hypersensitivity or intolerance to ridinilazole, vancomycin, and/or their excipients who are unwilling or unable to comply with protocol requirements, e.g. complete the full course of study treatment per schedule, attend study visits, report diarrhea/suspected recurrence, provide stool samples, ingest capsules/tablets or blood draws. |
| **Alter** | 18 Jahre und älter |
| **Prüfzentren** | **Innere Medizin 2** (Geschlossen)<br>Infektiologie<br>Theodor-Stern-Kai 7<br>60590 Frankfurt am Main<br>G. Neumann<br>Tel: 069 6301 4241 |
| **Sponsor** | Summit Therapeutics |
| **Registrierung in anderen Studienregistern** | ClinicalTrials.gov NCT03595566<br>EudraCT 2017-001642-10 (primäres Register) |