

Clinical Trial of Faropenem Against Acute Uncomplicated Cystitis in Women, Randomized, Open Labeled, Comparative Multicenter Study

Introduction and Objectives: Faropenem (FRPM) is the only oral penem used in Japan and this antimicrobial has low inducibility to be resistant. In the present study, efficacy of FRPM was investigated against acute uncomplicated cystitis (AUC) in women to determine the optimal periods of administration and to know the antimicrobial activities of FRPM to uropathogens.

Materials and Methods: A randomized, open labeled, comparative multicenter study was conducted on women with AUC at 35 participating institutions. FRPM with 200 mg, p.o. three times per day was administered to patients allocated to either the 3-day or 7-day administration group using the central registration method; a registration form of enrolled patients were faxed and allocated by the clinical trials office (CREC Net, Kitakyushu, Japan). Bacteriological investigation was conducted at Kyurin Corporation (Kitakyushu, Japan). Bacteriological and clinical efficacies were evaluated 5 to 9 days post-administration of FRPM. This study was approved by the ethics committee of CREC Net, Fukuoka, Japan.

Results: A total of 200 patients were registered between May 2010 and May 2011 (3-day administration: n=97; median age, 49 years old; age-range, 20-80 years. 7-day administration: n=103; median age, 47 years old; age-range, 21-81 years). By the exclusion criteria, 74 patients were excluded and the microbiological and clinical outcomes in 126 patients were analyzed. Microbiological outcome revealed that 7-day administration (n=64) was significantly more effective than 3-day administration (n=62) (eradication: 84.4% vs. 62.9%; persistence: 7.8% vs. 24.2%; relapse: 7.8% vs. 12.9%; $p=0.018$). The clinical outcome tended to be greater in 7-day administration than in 3-day administration, but differences were not significant. From the urine, 185 bacterial strains were isolated and *E. coli* was occupied 67.2%. The minimum inhibitory concentrations (MIC)₉₀ of cefcapene, FRPM, fosfomycin and levofloxacin for 119 *E. coli* strains were 0.5, 1, 4 and 1 µg/ml, respectively. FRPM proved effective against resistant strains comprising 2 strains in which the MICs of cefcapene were ≥ 4 µg/ml and 5 strains in which the MICs of levofloxacin were ≥ 8 µg/ml.

Conclusion: Seven-day administration of FRPM provides optimal administration period for AUC and FRPM was effective to resistant *E. coli* against cefcapene or levofloxacin.