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Bioequivalence of Fixed-Dose Repaglinide/Metformin Combination Tablet and Equivalent Doses of Repaglinide and Metformin Tablet: A Randomized, Single-Dose, Two-Period, Two-Sequence Crossover Study in Healthy Korean Male Volunteers

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The aim of this study was to evaluate the bioequivalence of a fixed-dose repaglinide/metformin combination (FDC) tablet at a dose of 2/500 mg with co-administration of equivalent doses of repaglinide (2 mg) and metformin (500 mg) as individual (EDI) tablets in healthy Korean male volunteers.This study was conducted as an open-label, randomized, single-dose, 2-period 2-squence crossover design in 48 healthy Korean male volunteers who received an FDC tablet or EDI tablets after a 12-hour overnight fast in each period. Plasma concentrations of repaglinide and metformin up to 24 hours were determined using a UPLC-MS/MS method. The pharmacokinetic parameters such as AUC0-t, AUC0-∞, C_{max}, T_{max} and $t_{1/2}$, were analyzed. Analysis of variance was carried out using logarithmically transformed AUC0-t, AUC0-∞ and Cmax. The formulations were considered bioequivalent if the log-transformed ratios of AUC_{0-t}, $AUC_{0-\infty}$, and C_{max} were within the predetermined bioequivalence range (80-125%) established by the US Food and Drug Administration. Tolerability was assessed throughout the study. No significant sequence effect was detected. The point estimates (90% CIs) for AUC_{0-t}, $AUC_{0-\infty}$ and C_{max} based on EDI tablets were 1.101 (1.023-1.185), 1.099 (1.022-1.184) and 1.126 (1.015-1.249) for repaglinide, and 0.952 (0.896-1.011), 0.950 (0.897-1.007) and 0.984 (0.927-1.045) for metformin, respectively, satisfying the bioequivalence criteria of 80-125% as proposed by the US FDA. This single-dose study found that both Repaglinide and Metformin in a fixed-dose combination tablet were bioequivalent to individual tablets of repaglinide 2 mg and metformin 500 mg in these fasting, healthy Korean male volunteers.

Biography

Yong-Bok Lee is currently a professor of the College of Pharmacy, the dean of Graduate School at Chonnam National University, and the president of The Korean Society of Pharmaceutical Sciences and Technology. He received his Ph.D. degree in Pharmaceutics from Seoul National University. Dr. Lee's research interests are focused on the lymphatic delivery of immunosuppressants, and the application of population PK/PD models associated with genetic differences in drug transporters and enzymes. He won many prestigious awards and honors including the KSPs Progress Prize and Academic Prize, the KFDC Academic Prize, the CNU Yongbong Academic Prize, and the MEST official commendation.

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