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Comparative bioequivalence study of two Rivaroxaban formulations in Iranian healthy volunteers

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It is a factor Xa inhibitor whose potent anticoagulant and antithrombotic effects have been demonstrated. This study was designed to evaluate the pharmacokinetics of a new generic formulation of rivaroxaban compared with a brand in healthy Iranian volunteers. Twenty-eight healthy volunteers enrolled in this study. This study employed a randomized, single-dose, two-way crossover method using oral tablets of either Axabin® or Xarelto®, as the test drug and reference drug, respectively. Two tablets (2×10 mg) were administered with 240 ml water. Blood samples were gathered at the following times: 0 hour (predose), and 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 24, and 30 hours after drug administration. To provide an accurate analysis, rivaroxaban plasma concentrations were determined by an UHPLC-MS/MS. The optimum separation was performed with a C18 column using acetonitrile and 10mM ammonium acetate (pH = 3, 70:30, v/v) as a mobile phase, at a flow rate of 0.3 ml/min. Precipitation of proteins was employed for extraction of rivaroxaban from the plasma samples. The quantification range for rivaroxaban was 2.5–600 ng.ml-1. According to FDA guidelines, the bioequivalence assessment's acceptable range is 80–125% at a 90% confidence interval (CI) for the mean ratios of test/reference formulation of the pharmacokinetic parameters. The 90% CI of parameters were AUC0-30 (82.02–98.31), AUC0-inf (82.4-100.34), and C_{max} (82.7–104.49). Therefore, the results proved the claim that the two formulations of rivaroxaban are bioequivalent.

Biography

Mohammad-Reza Rouini has completed his PhD from Tehran University of Medical Sciences and Post-doctoral studies from Ottawa University. He is the Director of Biopharmaceutics Lab at Faculty of Pharmacy. He has published more than 100 papers in reputed journals and has been serving as an Editorial Board Member of DARU.

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