Abstract

The objective of this study was to investigate the effect of antacid suspension on the pharmacokinetics of itraconazole. A randomized, two-way crossover study was conducted in twelve healthy Thai male volunteers. The first two days of the study, six healthy subjects received 30 ml of antacid suspension after meal and before bedtime. On the third day, a single dose of 200 mg of itraconazole was administered, followed by 3 doses of antacid suspension (Treatment A). Other six healthy subjects received only a single dose of 200 mg of itraconazole as the control groups (Treatment B). Following 1-week washout period, each group of healthy subjects received another treatment. The serum samples were analyzed by a validated HPLC-UV method. The results showed that the means ± SD of time to maximum serum concentration (t_{max}), maximum serum concentration (C_{max}) and area under the concentration-time curve (AUC) of itraconazole in the group with and without antacid were 5.1 ± 2.7 vs 3.0 ± 0.4 h ($p < 0.05$), 43.6 ± 16.9 vs 146.3 ± 70.5 ng/ml ($p < 0.001$), and 654.8 ± 452.2 vs 1928.5 ± 1114.6 ng•h/ml ($p < 0.05$), respectively. It can be concluded that itraconazole bioavailability was significantly reduced by antacid suspension. Consequently both drugs should not be administered concomitantly.