Bioequivalence study of stavudine 40 mg capsule

Sumana Chompootaweep, M.D., et, al
Faculty of Medicine, Chulalongkorn University

Abstract

The bioequivalence study of two oral formulations of stavudine were evaluated; Stavir® (Government Pharmaceutical Organization (GPO), Thailand) as the test formulation and Zerit® (Bristol-Myers Squibb company, USA), as the reference formulation. The two products were orally administered as a single dose of one 40 mg capsule of stavudine according to a randomized two-way crossover design to 26 healthy fasted Thai male volunteers. The washout period between treatment was 1 week. After drug administration, serial blood samples were collected at a specific time interval from 0-10 hours. The plasma stavudine concentration were determined via HPLC technique. Individual plasma stavudine concentration-time profile was analyzed for relevant pharmacokinetic parameters; the comparative bioavailability of the two products was determined by the analysis of variance (ANOVA) for two way crossover design, using logarithmic transformed data.

The results founds that the mean peak ($\bar{X}\pm SD$) plasma concentration (C_{max}) of Stavir® and Zerit® were 2.91±0.11 and 2.93±0.11 ng/mL, respectively. The 90% confidence interval for the difference of C_{max} mean was 86.49 - 105.44 %. The time to peak plasma concentration (T_{max}) of Stavir® and Zerit® were 0.8±0.38 and 0.7±0.33 hours, respectively. The difference time of peak plasma stavudine concentration was 14.28%. The mean area under the curve (AUC) of Stavir® and Zerit® were 3.32±0.08 and 3.33±0.07 ng.hr/mL, respectively. The 90% confidence interval for the difference of AUC mean was 92.15 - 103.63 %.

The present study revealed that the 90% confidence interval for the difference of C_{max} and AUC means were in the criteria of acceptance, which should be within 80-125%. Thus, this study demonstrated the bioequivalence of the test drug (Stavir®) and the reference drug (Zerit®).

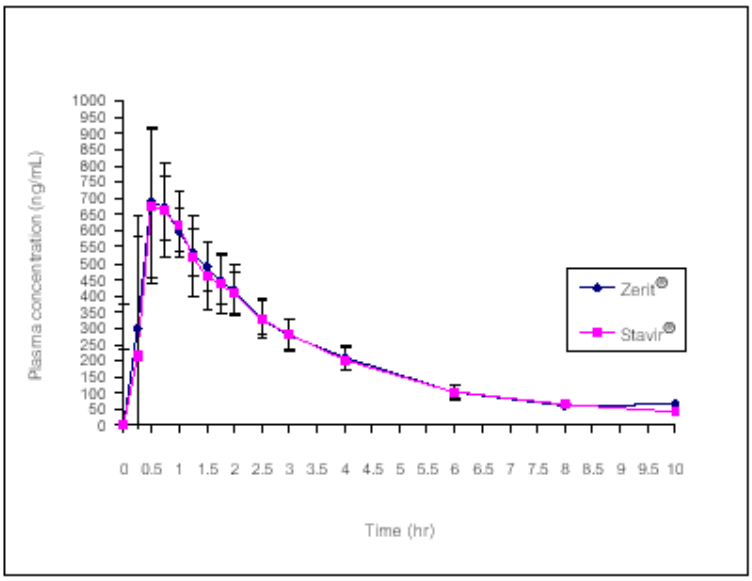

Figure 1 : Mean plasma stavudine concentration-time profiles from 26 subjects following a single oral dose of one 40 mg capsule of Stavir and Zerit®.