P11 COMPARATIVE PHARMACOKINETIC STUDY OF TWO-POSTCOITAL CONTRACEPTIVE AGENTS CONTAINING LEVONORGESTREL

Sumana Chompootaweep, Samai Leepipatpibal

Department of Pharmacology and Department of Obstetric & Gynaecology, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand.

ABSTRACT

The pharmacokinetic study was carried out on levonorgestrel tablets from two different sources (Hungarian-and Thai-made). Both preparations contained 0.75 mg levonorgestrel and had been used for postcoital contraception. Twelve-female subjects were given a single oral dose of 0.75 mg tablets in a crossover design. Plasma levonorgestrel concentration were determined via radio-immunoassay technique. The pharmacokinetic analysis of the levonorgestrel data was performed on the basis of a two-compartment open model using a M.K. model programme. Absorption and bioavailability of the Hungarian-made tablets were slightly higher as evidenced by higher serum concentrations of levonorgestrel in the first 2 hours. Thai-made tablets showed a slightly greater area under the concentration-time curve (AUC) during the first 24 hours. The volume distribution (Vd), the clearance (CL) and elimination half-life (T1/2) of both preparations were closely. Comparing the pharmacokinetic parameters (Cmax, Tmax, T1/2, CL, Vd, AUC) by using t-test were not statistically significant difference. It implied that both preparations (Hungarian-and Thai-made) were bioequivalent with each other.