

Population Pharmacokinetics of Clindamycin Hydrochloride Capsules in Chinese health subjects

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Abstract

Aim: The aim of the research is to establish a population pharmacokinetic (PPK) model of Clindamycin hydrochloride capsules in Chinese health subjects and investigate the factors affecting the pharmacokinetic parameters to provide guidance for the individualized treatment of Clindamycin. **Methods:** Clindamycin concentrations were measured in 48 selective health subjects (30 males and 18 females aged 18-45 years). The subjects were assigned to two groups randomly. 150mg Clindamycin oral administration were given at fasting or postprandial, respectively. Blood samples were collected at specified time. A total of 1344 blood drug concentration data were analyzed using NONMEM. The Non-linear mixed effect model was conducted to establish the population pharmacokinetic model of Clindamycin in Chinese healthy patients. The model was verified and evaluated by Visual Prediction Test (VPC) and Bootstrap method. **Results:** This study established a one-compartment pharmacokinetic model of Clindamycin hydrochloride capsules in Chinese healthy subjects. The final population pharmacokinetic parameters were oral absorption coefficient ($K_a=2.69 \text{ h}^{-1}$), apparent volume of distribution ($V/F=76.74 \text{ L}$) and apparent clearance ($CL/F=30.10 \text{ L}\cdot\text{h}^{-1}$). And the food was the only significant covariate in the model. The final model was stable and predictable, verified by VPC and Bootstrap. **Conclusion:** A robust and predictable population pharmacokinetic model of Clindamycin in Chinese healthy subjects was constructed successfully. The dietary state had a significant effect on the pharmacokinetics of Clindamycin which gave an important steer for dose adjustment or changing medication in clinical practice. Moreover, the model had great potential to guide the individualized medication of Clindamycin.

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