Pharmacokinetic Assessment in Early Phase Clinical Trials : Design and Data Analysis

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In the early clinical trials of a new drug, pharmacokinetic information such as bioavailability, absorption, distribution, metabolism, elimination, dose proportionality and the influence of food interaction must be obtained for the evaluation of safety, interindividual variations in drug response and for the optimum design of later phase clinical trials.

To fulfill the objectives of phase I study, the pharmacokinetic studies are usually incorporated as an essential part of single and multiple-dose safety and tolerance studies. Therefore pharmacokinetic study should be designed optimally with reasonable blood and biological fluid samplings. For this purpose the animal pharmacokinetic data obtained during preclinical phase of drug development may be extrapolated to human in first human trials. The common methods of pharmacokinetic scaling in mammalian species and optimum sampling strategies will be presented.

The optimum pharmacokinetic design to obtain parameters of Cmax, Tmax, AUC(area under the curve), volume of distribution, etc. will be discussed. And pharmacokinetic data handlings are to be demonstrated for the common situations of early phase clinical trials such as I.V. injection(bolus), I.V. infusion and oral dose studies.