

Bioavailability & Bioequivalence: BA/BE Studies Summit

August 29-31, 2016 Atlanta, USA

Some aspects of clinical trials on bioequivalence studies

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Under the conditions of financial resource shortage in public and/or insurance financing of health care, the high price of original drugs make for a high demand of generic drugs. The issue of the generic and original medication action identity on the human body is the main one for doctors and patients. One of the requirements imposed to generic drugs is the proof of their bioequivalence (pharmacokinetic equivalence) to the original ones. Clinical and Diagnostics Center (CDC) of the National University of Pharmacy is the first Ukrainian University hospital which specializes in running clinical trials with the participation of healthy volunteers. By the beginning of 2016 CDC has already gained wide experience and conducted more than 40 trials on studying bioequivalence. Selecting healthy volunteers carefully is one of the most important factors affecting the result of the study. From our point of view, it is not enough to merely assess volunteers' health status at their screening visit. It is also extremely important to assess the results of personal genotyping at least with respect to metabolic rate (fast or slow acetylators of isoniazid) at the pre-screening stage. This procedure will correspondingly increase the cost of the study but at same time it will provide more objective information and reduce the influence of genetic polymorphism on the results of the study.

Biography

Kateryna Zupanets has completed her PhD from National University of Pharmacy, Kharkiv, Ukraine. Currently, she is pursuing her Post-doctoral studies at Clinical and Diagnostics Center of the National University of Pharmacy. She is the author of more than 25 papers in reputed journals (5 articles for SCOPUS journals). She has been working as a Co-Investigator in more than 40 trials of Bioequivalence studies and Phase I at Clinical and Diagnostics Center of the National University of Pharmacy.

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