OMICS Group Conferences
Accelerating Scientific Discovery

3rd World Congress on
Bioavailability & Bioequivalence

March 26-28, 2012 Marriott Hotel & Convention Centre, Hyderabad, India

Evaluation of bioequivalence for endogenous molecules; Statistical impact of different basal levels correction procedures

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Several endogenous molecules, like thyroxine or insulin, are administered therapeutically. In this case pharmacokinetic profiles are, most often, a combination of levels coming by endogenous synthesis and those by exogenous uptake.

The development of similar products, both generics and new formulations, creates special problems of evaluation due to this pharmacokinetic situation sometime further complicated by the existence of endogenous feed-back mechanism controlling endogenous synthesis and/or release (i.e. thyroxine).

Leaving a part the use of approaches to minimize the influence by endogenous molecules (i.e. pharmacological blockade of endogenous synthesis, special subject groups and labeled products administration) the handling of pharmacokinetic data have been object of several discussions mainly trying to introduce corrections, like subtracting basal levels before exogenous administration, of the data recorded after exogenous administration.

In this presentation real data from three pharmacokinetic studies (a biliary salt, a corticosteroid and a flavonoid) will be shown and pharmacokinetic data will be evaluated applying different correction methods; all analytical determinations were performed by validated HPLC-MS/MS methods.

Keeping in consideration these results it has been observed that while a correction of basal levels is relevant to estimate absolute bioavailability data it is scarcely useful in BE estimations, the application of a statistic model used for steady state studies is equally effective and very similar results are estimated.

On the other side it has been found interesting to obtain PK data before exogenous drug administration to evaluate if PK curves are statistically different after treatment when compared to the circadian variations of endogenous levels.

Biography

Dr. S. Rizea Savu graduated in Medicine in Bucharest (Romania) in 1991 and obtained a Doctorate in Pharmacology in 2004. From 1992 to 2002 she was researcher in Pharmacology at the ICCF institute of Bucharest; in 1994, during a fellowship in Germany, has acquired expertise in HPLC-MS for bioanalytical applications. In 1996 she co-founded 3S-Pharmacological Consultation & Research GmbH, a German consultation company and CRO, focused on support, like clinical trials and analytical services, for pharmaceutical companies. In her scientific activity she contributed to several articles in international scientific journals.

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