

Towards understanding interchangeability of generic drugs

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Propositions

Towards understanding interchangeability of generic drugs

Yang Yu

1. In individual subjects, intrasubject variability plays a decisive role in difference in drug exposure of generic and the brand-name drug. The difference in drug exposure of generic and the brand-name drug is comparable with it of two occasions of generic or the brand-name drug.
2. Post-marketing variations in drug quality aspects do not seem to have impact on the demonstrated bioequivalence of a generic drug with the brand-name drug at the registration.
3. The current requirement for registration of a generic drug does not hamper interchangeability of generic and generic drugs.
4. The methods applied in the studies in the dissertation, such as inter-study comparisons and the model to evaluate cumulative impact of quality variations, can be used for further investigation.
5. Demonstration of bioequivalence between generic and the brand-name drug in healthy subjects can be extrapolated to patient populations.
6. It is difficult for biosimilar drugs to prove therapeutic equivalence with the brand-name drug via pharmacokinetic bioequivalence study. Investigation for the potential criteria of using pharmacodynamics parameters for demonstration of biosimilar is demand.
7. Switching to generic drugs from the brand-name drug is considered to not change the treatment in terms of effectiveness and safety. It however should not be interpreted as a support for switching the drugs in patients.
8. As legislation for ensuring bioequivalence between a generic and other generic drugs is not available, it is useful to repeat the investigation for generic-generic interchangeability after a couple of years when more and more generic drugs are registered.