OMICS Group Conferences
Accelerating Scientific Discovery

3rd World Congress on
Bioavailability & Bioequivalence

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

Does hemolysis affect the pharmacokinetic profile of drugs used in bioavailability studies

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The study is to reveal whether artificial hemolyzed blood samples obtained during clinical operation affect the pharmacokinetic (PK) profile and bioequivalence (BE) study results. A validated LC-MS/MS method was applied to analyze both hemolyzed and non-hemolyzed plasma samples derived from healthy volunteers to whom clopidogrel, methylprednisolone and ropinirole were administrated orally in three different pilot BE studies conducted in the clinical research center. During the first period of BE studies, for drug concentrations of hemolyzed and non-hemolyzed plasma samples, clopidogrel were 862.57±860.16 (pg/mL) and 920.61±959.14 (pg/mL) at 1 hour post dosing; methylprednisolone were 155.21±33.60 (pg/mL) and 160.01±29.9 (pg/mL) at 2.5 hours post dosing; ropinirole were 1322.87±392.96 (pg/mL) and 1151.42±299.91 (pg/mL) at 4 hours post dosing. During the second period, the values are 895.61±590.47 (pg/mL) and 941.60±601.91 (pg/mL) for clopidogrel; 160.01±29.99 (pg/mL) and 127.40±41.61 (pg/mL) for methylprednisolone; 1146.30±249.89 (pg/mL) and 1220.01±196.67 (pg/mL) for ropinirole. The drug concentration between hemolyzed and non-hemolyzed plasma samples did not yield a significant difference ($p>0.05$). In conclusion, although hemolysis may physically change the characteristics of the plasma samples, it doesn't significantly affet the accuracy of PK profile of clopidogrel, methylprednisolone and ropinirole. However, hemolysis should always be avoided in the practice of clinical studies to get ideal plasma for analysis.

Biography

Dr. Shengjun Zhang received his MD from Zhengzhou University in 1984 and his MBA in Health Management from Johns Hopkins University in 2010. He participated in clinical fellowship training at Stanford University Sleep Research Center; five years of cardiology postdoctoral training at NIA/NIH; two years of research experience at UMDNJ/RWJMS. In addition to research experiences, Shengjun worked two years in clinical research project management at Johns Hopkins School of Medicine Department of Oncology and two years of international clinical study in infectious diseases (HIV/AIDS) at Johns Hopkins Hospital (HPTN China study project coordinator). Shengjun also has two years of projects management and business development experience at Westat, Inc. and four years of executive-level project director experience at Frontage China Clincal Research Center. Currently he is a special appointed professor of Zhengzhou University First Affiliated Hospital. Prior to entering the clinical research and trial, he practiced internal medicine and pulmonary in China for twelve years.

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