Pharmaceut Reg Affairs 2012, 1:4
http://dx.doi.org/10.4172/2167-7689.S1.007

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Conference and Exhibition on
Pharmaceutical Regulatory Affairs

November 23-24, 2012 Hyderabad International Convention Centre, India

Pharmacokinetics and hepatic metabolism of ibuprofen under acute hypobaric hypoxia in rats

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Accession to high altitude (HA) causes environmental stress i.e. hypobaric hypoxia (HH) which may alter the hepatic metabolism and pharmacokinetics (DMPK) of drugs. As a result the drug dose required for safe and effective therapy may also vary at HA. The present study aims to evaluate the effect of acute hypobaric hypoxia (AHH) exposure on DMPK of ibuprofen. Experimental rats were exposed for 6 and 24 h duration at a simulated altitude of 7620m in decompression chamber. Ibuprofen at dose of 80 mg/kg body weight was administered orally. No statistically significant difference was observed in the PK variables in plasma of 6 h hypoxia exposed group. However, elimination half life (T½) and mean residence time (MRT) of ibuprofen significantly increased by 1.5 fold ($p < 0.05$) in 24 h hypoxia exposed group in comparison to unexposed group. A significant reduction in GST activity by 15% at 6 h and 23% at 24 h ($p < 0.05$) was observed in hypoxic group. The AST levels were significantly increased by 20-24% ($p < 0.05$) after AHH exposure. A significant down-regulated CYP2C9 protein level and mild histopathological changes were also observed after 24 h AHH exposure. Thus, the results imply that AHH exposure of 24 h cause alterations in phase II drug metabolism, CYP2C9 expression, PK and liver histology as well as liver function by ibuprofen under AHH. This could be therapeutically relevant, however, additional investigation under chronic hypoxic conditions is required.

Biography

Shefali Gola is pursuing her Ph.D from Bharathiar University, Coimbatore in Life Sciences. She is Senior Research Fellow at Defence Institute of Physiology and Allied Sciences (DIPAS), Defence R&D Organisation, Delhi.

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Nanotechnology: Challenges in harmonizing regulations

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Nanotechnology- manipulation of matter to 'nano-scale' is a new and exploding field but lacks 'technological innovation'. Nanotechnology enables high potential benefits for consumers and patients from novel applications on one hand and they may expose humans and the environment to new risks, which may interfere with the physiology of human and environmental species on the other. The regulatory challenge is therefore to outweigh the benefits from the risks. The key issues include: the wide variety of materials under nanotechnology (e.g. nanowires, nanotubes, nanodroplets, nanoparticles, nanocrystals, etc.), limited knowledge on the toxicity of nanomaterials (because they are not yet fully tested), lack of harmonised standards, the issues related to classification of nanomaterials (e.g. definition of nanomaterials, distinction compared to macro-substances). As with such scientific advances, it may not fit neatly into current regulatory regimes designed to address these concerns. Ongoing regulatory efforts are primarily focused on the national and regional level, while the international dimensions of nanotechnology governance are still poorly understood and rarely feature on the international agenda. With the ongoing globalization of nanosciences and the rapid expansion of international trade in nanomaterials, the demand for international coordination and harmonization of regulatory approaches is set to increase. Uncertainty both creates demand for and stands in the way of greater international cooperation and concordance of the regulations. Due to fast growth of the nanotechnological products there is an urgent need to clarify safety issues and identify gaps in occupational health safety, product and consumer safety or environmental regulations.

Biography

Shilpi Khattri is currently pursuing her 2nd year M. Pharma in Regulatory Affairs from JSS University, Mysore. She secured the highest marks in the 1st year of M. Pharma. She has done her graduation from Manipal University, Manipal. She published an article in a reputed journal titled Pharmacovigilance Regulations in India: A Step Forward. She has attended 63rd IPC and presented a poster on "Biologics Regulations in India: A Perspective" and also attended Indo-American Pharmaceutical Regulatory Symposium- 2011 and presented a poster on "Ameliorating Country's Pharmacovigilance Regulations".

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