World Academy of Science, Engineering and Technology
International Journal of Pharmacological and Pharmaceutical Sciences
Vol:8, No:09, 2014

A Randomised, Single-Dose, Two-Period, Cross-Over Phase I Pharmacokinetic Study to Compare TDS®-Diazepam with Rectal Diazepam in Healthy Adult Subjects

Authors : Faisal O. Al-Otaibi, Arthur T. Tucker, Richard M. Langford, Stuart Ratcliffe, Atholl Johnston, Terry D. Lee, Kenneth B. Kirby, Chandan A. Alam

Abstract : The Transdermal Delivery System (TDS®) is a proprietary liquid formulation that can be applied to intact skin via a metered pump spray to facilitate drug delivery to the circulation. The aim of this study was to assess the ability of the TDS preparation to deliver diazepam systemically, and to characterize the pharmacokinetic profile of the drug in healthy adult subjects. We conducted a randomized, single-dose, two-period, crossover phase I (pharmacokinetic) comparative study in twelve healthy volunteers. All volunteers received both 10 mg TDS-diazepam topically to the upper chest and 10 mg of the rectal diazepam preparation (Diastat®, 10 mg diazepam gel), with a minimum washout of 14 days between dosing episodes. Both formulations were well tolerated in all volunteers. Following topical application of TDS-diazepam, the mean AUC0-72h was 1241 ng/mL.h and the Cmax 34 ng/mL. The values for rectal Diastat were 4109 ng/mL.h and 300 ng/mL respectively. This proof of concept study demonstrates that the TDS preparation successfully delivered diazepam systemically to adults. As expected, the concentration of diazepam following the TDS application was lower and not bioequivalent to rectal gel. Future development of this unique system is required.

Keywords : transdermal delivery system, diazepam, seizure, bioequivalence, pharmacokinetic
Conference Title : ICPP 2014 : International Conference on Pharmacy and Pharmacology
Conference Location : London, United Kingdom
Conference Dates : September 26-27, 2014