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Influence of menstrual cycle on the pharmacokinetics of antibiotics

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For several reasons no two individuals can be considered identical and hence individualization of therapy is the current trend in treating the patients. When no two individuals are considered identical, it is inappropriate to extend the data obtained in men in clinical research to females and thus, the new concept of a “gender frame work for health research” is gaining importance in recent years. Influence of menstrual cycle on the pharmacokinetics of Doxycycline. Twelve healthy female volunteers have been included in the study after obtaining written informed consent. The age ranged from 16 to 25 years and weight was from 40 to 60 kg respectively. None of the participants had received any medication during two weeks prior to the study. Experimental design: The volunteer selection and recruitment will be carried out after obtaining informed consent from each volunteer. The drug administration will be done to each volunteer at 7 am along with a glass of water after an overnight fasting on 3rd, 13th and 23rd day of menstrual cycle. No food and drinks will be allowed to be taken by the subjects for about 4 hours after drug administration. After that they will be allowed to take regular meals. Blood samples (2.5 ml) will be drawn into tubes. A pre-dose blood sample will serve as an analytical blank. The blood samples will be obtained at 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 7, 9 & 12 hrs after dosing along with a blank sample before administering the drug. The blood samples will be centrifuged at 2000 rpm for 15 minutes. These blood samples will be stored under frozen conditions until HPLC analysis.

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