## Interchangeability of Two 500 Mg Amoxicillin Capsules with One 1000 Mg Amoxicillin Tablet After a Single Oral Administration

Preferred Abstract (Original):

The aim of the study was to evaluate if two capsules (Amoxil® capsules, 500 mg/capsule) and one tablet (Amoxicare® tablets, 1000 mg/tablet) of amoxicillin have similar bioequivalence parameters. For this purpose a randomized, two-way, crossover, bioequivalence study was performed in 24 healthy, male volunteers, divided into two groups of 12 subjects each. One group was treated with the reference standard (Amoxil®) and the other one with the generic tablet Amoxicare®, with a crossover after a wash-out period of 7 days. Blood samples were collected at fixed time intervals and amoxicillin was determined by a validated HPLC method. The pharmacokinetic parameters AUC0-8, AUC0-∞, Cmax, Tmax, Ke and T1/2 were determined for both formulations and statistically compared to evaluate the bioequivalence between the two brands of amoxicillin, using the statistical model recommended by the FDA. Cmax and AUC0-∞ were statistically analyzed using analysis of variance (ANOVA); no statistically significant difference was observed between the two formulations. The 90% confidence intervals between the mean values of Cmax and AUC0-∞ fall within the FDA specified bioequivalent limits (80-125%) suggesting that the two products are bioequivalent and the two formulations are interchangeable. Based on these findings it was concluded that the practice of interchangeability between the above formulations to achieve better patient compliance could be followed without compromising the extent of amoxicillin absorption.