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A single blind, balanced, randomized, single period, comparative palatability evaluation study of four flavored, marketed, antimicrobial drugs with quinine and among themselves in healthy adult human subjects under fasting condition

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Objective: To evaluate palatability of antimicrobial drugs in Indian healthy adult human volunteers.

Design: In a taste test, four antimicrobial agents cefpodoxime (pineapple flavour), erythromycin estolate (orange flavour), cefixime (banana flavour) and ofloxacin (mint flavour) were compared with quinine as positive control.

Subjects: 24 healthy male volunteers were selected based on pre- study training. Intervention: Study was approved by IRB and informed consent was obtained from all volunteers. Palatability was determined using a single blind taste test of four flavoured antimicrobial agents. After each drug administration (sip and spit), volunteers were asked to rate palatability using visual analogue scale (VAS) incorporating a facial hedonic scale at every 5 minutes upto 0.50 hours using a one-way analysis of variance for repeated measures. Results: All volunteers were young males 25.4±5.7 years (mean ± SD) with normal BMI (22±1.7). The mean palatability scores for quinine, cefpodoxime, erythromycin, cefixime and ofloxacin were 1.08±0.83, 3.04±2.46, 4.13±2.58, 8.54±0.88 and 6.50±2.45 respectively. All antibiotics were more palatable when compared with Quinine ($p<0.001$). Amongst the four antibiotics, cefixime was the most palatable ($p<0.001$) and cefpodoxime was least palatable ($p<0.001$). 100% subjects felt quinine was bitter and cefixime was sweet.

Conclusion: Current study, consistent with the literature has demonstrated the utility of palatability assessment using VAS with a facial hedonic scale in an Indian context. Evaluation of palatability techniques should be part of the routine strategy in Indian formulation development intended for infants and children usage.

Biography

Sunil Kapur has extensive experience in clinical development, business development and commercial analysis consulting in the Biopharma Industry having worked in multinational organizations like Philip Morris USA, Altria, Daiichi Sankyo Pharma and Piramal Healthcare in the US and India. He has a medical degree from India, Masters (Immunology) and a MBA certification from the US with 15 posters/publications in international journals. He is a member of American Society for Clinical Pharmacology and Therapeutics (ASCPT), American College of Clinical Pharmacology (ACCP), and Bombay Management Association (BMA).

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