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A strategy to conduct a dental trial

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The primary objective would be to compare the analgesic efficacy of two formulations versus placebo in terms of onset of action to be measured by total pain relief (TOTPAR) at 60 minutes post dose. Subjects who would experience moderate to severe pain as demonstrated by a verbal rating scale (VRS) and confirmed by a visual analogic scale (VAS) within 4 hours of out-patient surgical removal of partially or fully impacted third molars under local anaesthetic would be receiving either 1 gram of XX as a tablet, 1 gram of YY, the generic equivalent in a different formulation, or matching placebos. Over the 4 hour period immediately after dosing, subjects would rate pain relief periodically and a single blood sample would be collected at 65 min post dosing to verify analgesic blood concentration as a pharmacokinetic component. A sufficient number of subjects will be screened at clinical sites to ensure that qualified subjects would be scheduled for oral procedure. An estimated number of subjects who undergo the surgical procedure will reach the necessary pain level within the designated 4 hour post-surgery time period. Hence, the subjects who meet the minimum pain threshold will be randomly assigned to one of the treatment groups. Rescue medication would be kept handy. Each subject will be enrolled in the study for up to five weeks. The duration of the study would be approximately 3 to 4 months. The assessment of safety will be based on adverse events reported by all subjects following dosing with the study medication.

Biography

Shabana Khan, a medical professional by background and a post graduate in clinical research and international regulatory affairs, is currently associated with Ecron Acunova. Her domain and expertise lies in analyzing the feasibility and pharmaceutical market research for the conduct of clinical trials in various therapeutic areas, globally, along with sound knowledge of project management activities; Her current interest is in exploring the guidelines framed by different regulatory agencies towards the biosimilars which possess the clear potential for payers in the emerging "pharmerging" markets, such as India, Brazil and China.

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