

A multicentric, open-label, interventional, non-comparative study to evaluate the efficacy and tolerability of a poly-herbal topical balm for pain relief in subjects with headache (VIN-ACHE).

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Statement of the problem: Primary headache disorders are associated with substantial personal suffering and impaired quality of life. Tension-type headache (TTH) is the most common primary headache disorder. Topical herbal medicines though not the most potent analgesics, are a popular alternative in Indian medicine for mild to moderate headache. This study was conducted to evaluate the efficacy, tolerability, subject satisfaction and user perception of a pain relief balm (Ayurvedic proprietary medicine) containing multiple herbal ingredients in 65 adult Indian subjects with TTH.

Methodology & Theoretical Orientation: This was a multicentric, open-label, interventional, single-arm study. Subjects with pain score $>4/10$ in the past one week were advised to apply the pain relief balm on forehead and massage it gently, within 2 hours of onset of headache. Repeat application was allowed, if needed. Efficacy was evaluated by time to: onset of action (i.e. cooling/warmth/tingling/burning sensation), onset of pain relief and achievement of complete pain relief (0-120 minutes post dose). Pain relief was measured using numeric pain rating scale (0-10). Subject satisfaction and user perception was evaluated on 7-point Likert Satisfaction scale.

Findings: Post the single application, mean (\pm SD) time to: onset of action was 37.29 (\pm 16.13) seconds, onset of pain relief was 3.83 (\pm 1.76) minutes and achievement of complete pain relief was 19.21 (\pm 12.85) minutes. 92.3% of subjects were very-satisfied to satisfy with the pain relief. All the subjects were very-satisfied to satisfy for ease of application, ease of spreading and stickiness (except greasiness). No adverse event was reported during the study.

Conclusion: The pain relief balm was found to be effective with rapid onset of action, in relieving headache and was well tolerated.

Biography

Dr. Poonam Rohira has completed her graduation in Bachelor of Medicine and Bachelor of Surgery (MBBS) followed by post-graduation in Doctorate of Medicine (MD) in Pharmacology from University of Mumbai (India) in 2001. She has been associated with academia (medical schools) and with various functions in the pharmaceutical industry like medical affairs, regulatory affairs, clinical research (clinical operations & medical monitoring), medical writing, pharmacovigilance and medical operations.

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