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CODEINE PLUS ACETAMINOPHEN FOR PAIN AFTER PHOTOREFRACTIVE KERATECTOMY: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED ADD-ON TRIAL

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Background: Pain after photorefractive keratectomy (PRK) is significant, and the analgesic efficacy and safety of oral opioids in combination with acetaminophen has not been fully investigated in PRK trials.

Objective: To assess the efficacy and safety of the combination of codeine plus acetaminophen (paracetamol) versus placebo as an add-on therapy for pain control after PRK.

Study Design: Randomized, double-blind, placebo-controlled trial.

Setting: Single tertiary center

Methods: One eye was randomly allocated to the intervention, whereas the fellow eye was treated with placebo. Eyes were operated two weeks apart. Participants include adults (>20 years) with refractive stability for ≥1 year, who underwent PRK for correction of myopia or myopic astigmatism. Codeine (30 mg) plus acetaminophen (500 mg) were given orally at 4 times/day for 4 days after PRK. Follow-up is for 4 months. Outcomes are pain scores at 1-72 h as measured by the visual analogue scale (VAS), McGill Pain Questionnaire (MQP) and Brief Pain Inventory (BPI), adverse events (AEs) and cornea wound healing. Trial registration: NCT02625753.

Results: Of the initial 82 eyes, 80 completed the trial (40 interventions, 40 placebos). Median (interquartile range) pain scores as measured by the VAS were statistically and clinically lower during treatment with codeine/acetaminophen compared to the placebo: 1h: 4 (2-4) vs 6 (3-6), p< 0.001; 24 h: 4 (3-6) vs 7 (6-9), p< 0.001; 48 h: 1 (0-2) vs 3 (2-5), p< 0.001; 72 h: 0 (0-0) vs 0 (0-2), p=0.001). Virtually identical results were obtained by the MQP and BPI scales. The most common AEs with codeine/acetaminophen were drowsiness (42%), nausea (18%) and constipation (5%). No case of delayed epithelial healing was observed in both treatment arms.

Conclusions: When added to the usual care therapy, the oral combination of codeine/acetaminophen was safe and significantly superior to placebo for pain control after PRK.

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