Study Protocol

Title: Analgesic Effects of Intranasal Diclofenac Sodium, Ibuprofen, and Paracetamol in Pediatric Tonsillectomy Cases

Document Date: 11/12/2024

NCT Number: NCT06731556

Unique Protocol ID: 20.08.2021-E.28962

Objective: This study aims to evaluate the efficacy and safety of intranasal diclofenac sodium, ibuprofen, and paracetamol for postoperative analgesia in pediatric tonsillectomy patients.

Study Design:

- Prospective, randomized study.

- Participants: 60 children aged 2–14 years.

- Groups:

- Group 1: Intranasal paracetamol.

- Group 2: Intranasal diclofenac sodium.

- Group 3: Intranasal ibuprofen.

- Group 4: Intravenous paracetamol.

Outcome Measures:

- Primary: Pain levels assessed via CHEOPS, VAS, and Wong-Baker modified VAS.

- Secondary: Safety parameters and side effects.

Ethical Approval:

- Approved by the Clinical Research Ethics Committee of Bezmialem Vakıf University on 20/08/2021, decision number 3/24.

Procedures:

The drugs were prepared at the Faculty of Pharmacy, Bezmialem Vakıf University.

The patients were divided into four groups to control post-operative analgesia: Intranasal paracetamol (Group 1), Intranasal diclofenac sodium (Group 2), Intranasal ibuprofen (Group 3), and Intravenous paracetamol (Group 4). Patients with pathologies such as chronic sinusitis, cold, rhinitis, turbinate hypertrophy, nasal polyposis, deviated septum, impaired mucociliary clearance, and atrophic rhinitis were excluded.

Pain levels were assessed using the Modified Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) established by McGrath et al. . In this postoperative pain assessment, behavioral scoring (crying, facial expression, verbal complaints, body position, leg movements, and touching the wound) was evaluated by an experienced observer. The Wong-Baker modified VAS scoring system was used for children aged 4-8 years, and the VAS scoring system was used for children aged 9-15 years . Pain levels were recorded by an independent observer at 15, 30, 60, 120 minutes and 4, 6, 12 hours after the end of surgery.

All patients underwent the same surgical procedure. Electrocardiography, noninvasive blood pressure and pulse oximetry were performed in all patients after admission to the operating room. For induction of general anesthesia, 1 mg/kg lidocaine, 1 μg/kg fentanyl, and 2-2.5 mg/kg propofol were administered. Patients were ventilated in volume control mode with FiO_2: 0.5, tidal volume: 6-8 mL/kg, frequency: 15-22/min, and end-tidal carbon dioxide: 30-35 mmHg. Sevoflurane (1.5%-2%) in a 50%:50% medical air: oxygen mixture was used for anesthesia maintenance.

Postoperative pain, sedation, and side effect measurements were recorded objectively by a blinded observer.

Data Management:

- Data collected by independent, blinded observers.