Study Protocol

Title: Effects of Topical Bromfenac Solution on Macular Thickness in Cataract Patients Undergoing Phacoemulsification Surgery

Clinical Trial Registration Number: NCT06785090

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1. Background and Rationale

Cystoid macular edema (CME) is a common postoperative complication following cataract surgery. Bromfenac, a topical nonsteroidal anti-inflammatory drug (NSAID), is hypothesized to reduce macular thickness and prevent CME. This study investigates the efficacy and safety of bromfenac in patients undergoing phacoemulsification.

2. Study Objectives

- **Primary Objective:** To assess the effect of bromfenac 0.09% ophthalmic solution on macular thickness after phacoemulsification.
- **Secondary Objective:** To evaluate potential adverse effects, including corneal erosion.

3. Study Design

- **Study Type:** Randomized controlled trial
- **Allocation:** Randomized
- **Intervention Model:** Parallel assignment
- **Masking:** Single-blinded (Investigator)

4. Eligibility Criteria

Inclusion Criteria:

1. All patients 18 years of age and older.
2. Patients diagnosed with cataracts.

Exclusion Criteria

1- Patients less than 18 years of age.
2- Patients with glaucoma, ocular hypertension, pseudo-exfoliation syndrome, or any optic nerve disease.
3- Patients with ocular diseases that might influence macular thickness, such as age-related macular degeneration, epiretinal membrane, history of uveitis, intraoperative complications, and traumatic cases.
4- Patients have undergone previous ocular surgery in the same eye, such as vitrectomy, intravitreal injection, retinal laser therapy, or corneal surgery
5- Patients who developed severe adverse effects from other drugs or had complications intraoperatively or postoperatively unrelated to bromfenac.
6- Patients take antiglaucoma medications.

7- Patients lost to follow-up.
8- Patients with an allergy to one of the postoperative medications.

5. Intervention and Follow-up

- **Group one-** consisted of forty-five patients who received 0.09% bromfenac ophthalmic solution twice daily in addition to Moxifloxacin 0.5% ophthalmic drops every 6hrs and Dexamethasone phosphate 0.1% ophthalmic drops every 4-6hrs.
- **Group two-** consisted of forty-two patients who received only Moxifloxacin 0.5% every 6hrs and Dexamethasone phosphate 0.1% ophthalmic drops every 4-6hrs without the administration of bromfenac 0.09% ophthalmic drops.

6. Outcome Measures

- **Primary Outcome:** Change in central macular thickness (CMT) measured by Optical Coherence Tomography (OCT)
- **Secondary Outcomes:** adverse effects

7. Statistical Methods

- Sample size calculation based on a power of 80% and significance level of 0.05.
- Independent t-test for intergroup comparisons.
- Paired t-test for intragroup pre- and post-treatment comparisons.

Statistical Analysis Plan (SAP)

1. Introduction

This SAP outlines the statistical methodologies for analyzing data collected in the clinical trial titled "Effects of Topical Bromfenac Solution on Macular Thickness in Cataract Patients Undergoing Phacoemulsification Surgery."

2. Study Population

- **Intent-to-Treat (ITT) Population:** All randomized patients.
- **Per-Protocol (PP) Population:** Patients who adhered to treatment and completed follow-up assessments.

3. Statistical Methods

- **Descriptive Analysis:** Means and standard deviations (SD) for continuous variables.
- **Inferential Analysis:**

- **Primary Outcome:** Two-sample t-test for between-group comparisons of CMT change.
- **Secondary Outcomes:**
  - Incidence of CME: Chi-square test.
  - Adverse effects: Fisher's exact test.

4. Handling of Missing Data

- **Missing data <5%:** Complete case analysis.
- **Missing data >5%:** Multiple imputation methods.

5. Software Used

All analyses will be performed using SPSS.