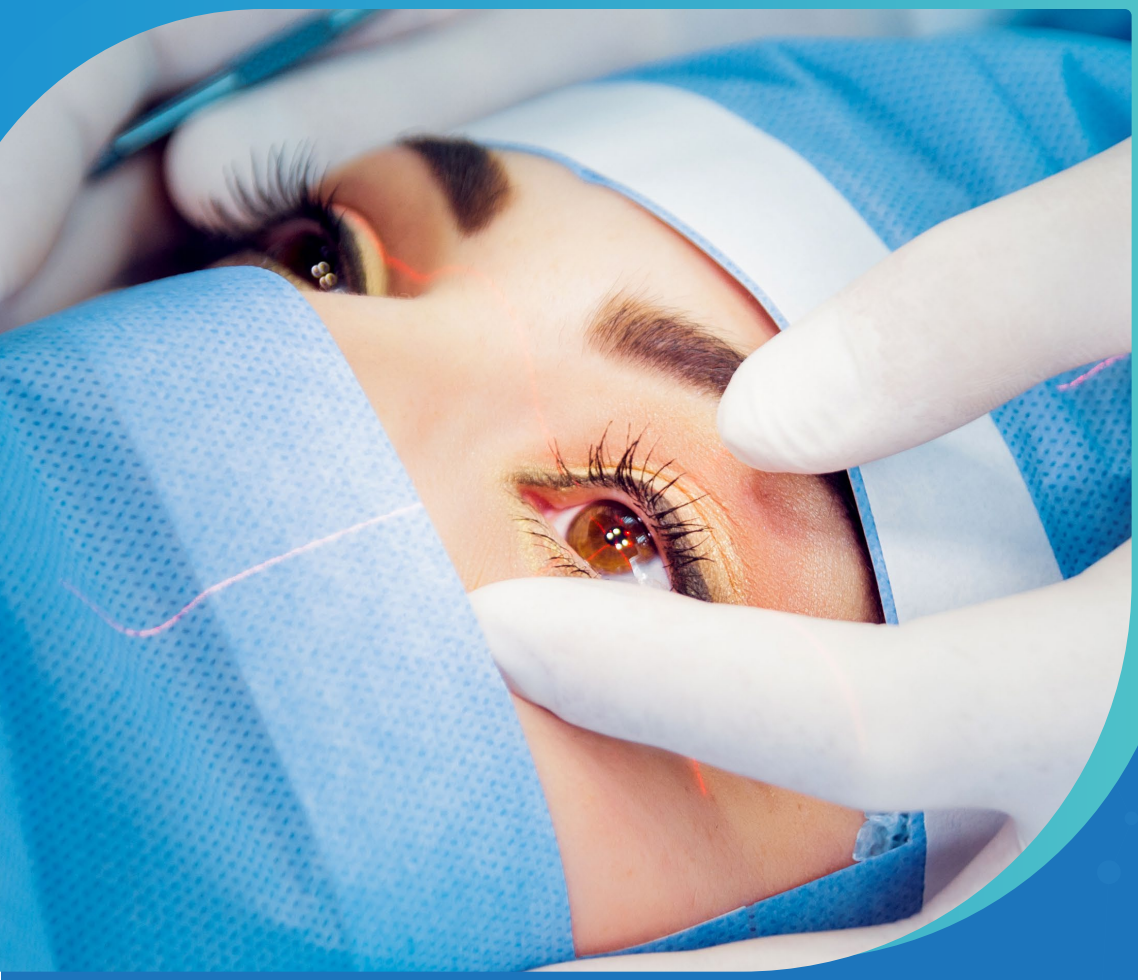


veeda clinical research®

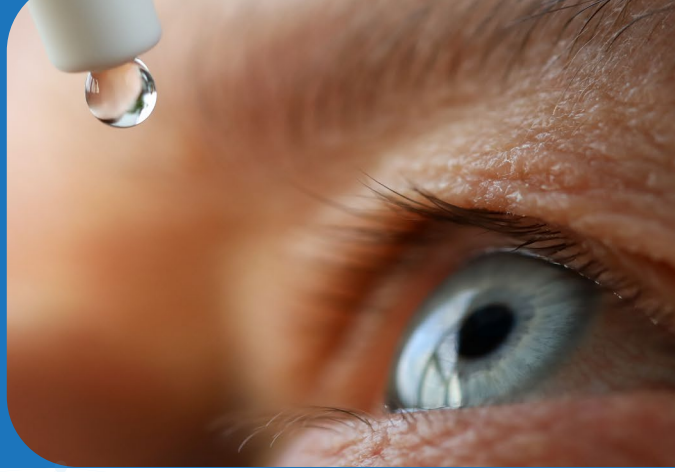
Evaluating the **Bioequivalence of Brinzolamide & Brimonidine** for the treatment of **Open-angle Glaucoma**

Type of Study

A multicentre, randomized, assessor-blinded, active-controlled, parallel group, two arm, non-inferiority clinical trial for the comparison of efficacy and safety of a preservative-free Brinzolamide & Brimonidine tartrate eye drops suspension

Situational Analysis

To evaluate bioequivalence by establishing non-inferiority between test and reference product



Veeda supported the client in following services for the successful execution of the study

- Study Design & Execution
- Project Management
- Ethics Committee Submission
- Providing regular CRA Training
- Trained & Skilled Personnel like Optometrist trained for BCVA to perform ETDRS method
- Patients Recruitment and Retention with Inclusion & Exclusion Review
- Site Management & Monitoring with Identification & Selection of potential Investigators with necessary study equipment
- Investigational Medicinal Product (IMP) Management
- Regulatory Support & Guidance
- Data Management & Biostatics
- Medical Writing & Lab Logistics

Highlights of Results Delivered

233 Patients Screened
196 Patients Randomized

All the study objectives were achieved

84 days of Treatment Duration with no SAE Reported

12 Sites involved & Less than **4** months to complete the Clinical Part of the study

Safety Assessment parameters assessed throughout the study as below

- Ophthalmic Assessments including Perimetry & Pachymetry, IOP measurement with calibrated Goldman Applanation Tonometer, Gonioscopy, Indirect Ophthalmologic/ Fundus examination
- Clinical Laboratory Assessments
- Adverse Events Monitoring
- Vital Signs Measurement
- Topical Administration of Eye drops / IMPs regularly as prescribed

Challenges & Veeda's Action Plan

Challenges	Action Plan
Availability of skilled staff at sites and equipment to perform study-specific ophthalmic examinations uniformly across all sites	Investigator sites were selected based on the availability of skilled staff and required equipment (e.g. Calibrated Goldman Applanation Tonometer)
Successful recruitment of patients was the most challenging aspect	Effective site selection, patient database availability at sites, frequent follow-ups for patient recruitment, and continuous monitoring at sites helped in achieving the required patient enrolment
IMP administration compliance: Patient-self IMP administration regularly as per study requirements at home was challenging	Patients were very well explained and trained by the study pharmacist for IMP administration and instructions, which were provided in the patient diary, and took regular follow-ups with the patient

Results

- The non-inferiority was established in terms of efficacy and safety of Brinzolamide & Brimonidine tartrate eye drops suspension (Test product Vs Reference Product) in adult patients with open-angle glaucoma or ocular hypertension
- The study was completed successfully in compliance with protocol requirements