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Abstract Information

Abstract Title:
The European Glaucoma Prevention Study (EGPS) Group.

Purpose:
The European Glaucoma Prevention Study (EGPS) seeks to evaluate the efficacy of reduction of intraocular pressure (IOP) by dorzolamide in preventing or delaying primary open-angle glaucoma (POAG) in patients affected by ocular hypertension (OHT).

Design:
Randomized, double-masked, controlled clinical trial.

Participants:
One thousand eighty-one patients (age, ≥ 30 years) were enrolled by 18 European centers. The patients fulfilled a series of inclusion criteria, including : IOP 22 to 29 mm Hg; 2 normal and reliable visual fields (on the basis of mean deviation and corrected pattern standard deviation or corrected loss variance of standard 30-2 Humphrey or Octopus perimetry); normal optic discs as determined by the Optic Disk Reading Center.

Main Outcome Measures:
Efficacy end points were visual field, optic disc changes, or both. A visual field change during follow-up had to be confirmed by 2 further positive tests. Optic disc change was defined on the basis of the agreement of 2 of 3 independent observers evaluating optic disc stereo slides. The safety end point was an IOP of more than 35 mm Hg on 2 consecutive examinations.

Methods:
Patients were randomized to treatment with dorzolamide or placebo (the vehicle of dorzolamide).

Results:

During the course of the study, the mean percent reduction in IOP in the dorzolamide group was 15% after 6 months and 22% after 5 years. Mean IOP declined by 9% after 6 months and by 19% after 5 years in the placebo group. At 60 months, the cumulative probability of developing an efficacy end point in the dorzolamide group was 13.4%, and 14.1% in the placebo group (hazard ratio, 0.86; 95% confidence interval (CI), 0.58-1.26; P = 0.45). The cumulative probability of developing an efficacy or a safety end point in the dorzolamide group was 13.7%, and 16.4% in the placebo group (hazard ratio, 0.73; 95% CI, 0.51-1.06; P = 0.1).

Conclusion:
Dorzolamide reduced IOP by 15% to 22% throughout the 5 years of the trial. However, the EGPS failed to detect a statistically significant difference between medical therapy and placebo in reducing the incidence of POAG among a large population of OHT patients at moderate risk for developing POAG, because placebo also significantly and consistently lowered IOP.