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Prophylactic Ranibizumab for Exudative age-related macular degeneration (AMD) in Vulnerable Eyes with Non-exudative AMD Trial (PREVENT): A prospective controlled clinical trial

Maziar Lalezary, MD
Beverly Hills, CA

Clement K Chan, MD, FACS, Prema Abraham, MD, Michael Elman, MD, Steven Lin, MD, Rahul N. Khurana, MD, Alok Bansal, MD, Mark R Wieland, MD, James Palmer, M.D., Glenn Yiu, MD, PhD, Brandon J Lujan, MD

Purpose:

To present final results of PREVENT, a clinical trial investigating the role of prophylactic intravitreal ranibizumab in high-risk eyes with nonexudative AMD (NE-AMD) in patients diagnosed with exudative AMD (Ex-AMD) in the fellow eye.

Methods:

PREVENT was a multicenter, prospective, randomized, single-masked, controlled, interventional investigator-sponsored phase I/II comparative trial. Study eyes with NE-AMD at risk for Ex-AMD (≥ 1 or large druse or multiple intermediate drusen, hyperpigmentation) with Ex-AMD in the fellow eye diagnosed within 5 years were enrolled from 108 patients. Study eyes were randomized (1:1) to 0.5 mg ranibizumab (IVR) versus SHAM injections for every 3 months (M) for 24 M. Fundus Reading Center (same day confirmation of diagnosis) before enrollment (Glenn Yiu, UC Davis) and independent SD-OCT assessment (Brandon Lujan) evaluating macular attributes (macular thickness and volume, drusen volume and area, area of atrophy, etc) were performed. ETDRS best-corrected visual acuity (BCVA), intraocular pressure, ophthalmic examination, spectral-domain optical coherence tomography (Zeiss, Cirrus), fundus photography, autofluorescence, and fluorescein angiography were obtained at baseline and every 3M for 24M. Adverse events were monitored. The primary outcome measure was conversion to exudative AMD.

Results:

All 108 patients have been enrolled (54 [50%] IVR, 54 [50%] SHAM). All were Caucasians (61 females, 47 males). Mean age was 77.8. Mean best-corrected visual acuity was (20/28, 77.7 letters) at baseline, and (20/31, 74.9 letters) at last follow-up (p=0.08, Wilcoxon signed rank test). Early termination was noted in 17 patients, which were similarly distributed in both groups (9 in SHAM, 8 in IVR). With completion of follow-up, 14 eyes (13%) have converted to Ex-AMD (7 of 54 [13%] in SHAM [at 1M, 3M, 6M, 12M, 18M, 18M, 18M] and 7 of 54 [13%] in IVR [at 3M, 9M, 9M, 9M, 15M, 24M, 21M]). No adverse events have been noted.

Conclusions:

After 2-year follow-up, conversion to Ex-AMD in high-risk NE-AMD eyes was equal (7 of 54; 13%) in the SHAM and IVR Group. Quarterly intravitreal ranibizumab in high-risk NE-AMD eyes did not prevent conversion to Ex-AMD.