

PIER: Year 1 FA/OCT Results in a Study of Ranibizumab (Lucentis™) for Choroidal Neovascularization (CNV) Due to Age-related Macular Degeneration (AMD)

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PURPOSE

PIER is a 2-year study of the safety/efficacy of 0.3- and 0.5mg doses intravitreal ranibizumab, injected monthly for 3 doses and then every 3 months, vs. Sham injections in AMD patients with CNV lesions with or without classic CNV. Fluorescein angiography (FA) and optical coherence tomography (OCT) were used to assess morphologic changes in CNV lesions over time in the 3 groups.

METHODS

In this multicenter, double-masked, controlled trial, patients were randomized 1:1:1 to 0.3mg ranibizumab, or 0.5mg ranibizumab, or sham injections. A total of 10 ranibizumab or sham injections may be administered during the 2-year study period (6 during the first year). Changes in CNV lesion morphology are being assessed using fundus photography and FA at all study sites, and OCT at selected sites (approx. 123 patients at 24 sites). During year 1, FA and photos were obtained at screening and Months 3,5,8 and 12 and OCT on Day 0 and Months 1,2,3,5,8 and 12. An independent central reading center performed masked review of the images.

RESULTS

Between September 2005 and March 2006, 184 patients were enrolled and randomly assigned 1:1:1 to 0.3mg ranibizumab, 0.5 mg ranibizumab, or sham injections. At the time of abstract submission, the study is still masked. Therefore, results for the first year were not yet available, but they will be presented at this meeting.

CONCLUSION

Twelve-month FA and OCT data from the Phase IIIB PIER trial of ranibizumab treatment of subfoveal neovascular AMD will be presented.