

An OCT-guided Variable-dosing Regimen with Lucentis™ (Ranibizumab) in Neovascular AMD: One Year Results from the PrONTO Study

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PURPOSE

To determine if an OCT-guided variable dosing regimen with Lucentis (Ranibizumab, Genentech, Inc.) can maintain the improved visual acuity (VA) achieved in neovascular AMD patients after 3 sequential monthly Lucentis injections, we initiated a single-site study known as the Prospective OCT Imaging of Patients with Neovascular AMD Treated with Intra-Ocular Lucentis (PrONTO) Study.

METHODS

Neovascular AMD patients with VA from 20/40 to 20/400 and OCT central retinal thickness measurements of at least 300 μm were enrolled. Each patient received 3 consecutive monthly injections of Lucentis (500 μg) in their study eye beginning at baseline. VA and OCT measurements were obtained at baseline and monthly thereafter. Fluorescein angiography was performed at baseline and every 3 months. Retreatment with Lucentis was performed only if one of the following occurred: an increase in central OCT thickness of at least 100 μm , a loss of 5 letters in conjunction with recurrent fluid detected by OCT, new onset classic neovascularization, or new macular hemorrhage.

RESULTS

Forty patients were enrolled. By Month 3, 1 month after the last scheduled injection, the mean VA score improved by 10 letters ($p < 0.001$) and the mean central thickness measurement decreased by 190 μm ($p < 0.001$). By Month 7, 5 months after the last scheduled injection, the average number of retreatments per eye was 0.2 with 50% of eyes receiving no additional treatment. The most common reason for retreatment after the last scheduled injection at Month 2 was evidence of fluid detected by OCT in association with a 5 letter decrease in visual acuity. As the neovascularization recurred, OCT identified changes in macular anatomy prior to changes in visual acuity. By Month 7, the mean VA improved by 9 letters ($p < 0.001$) and the mean central thickness measurement decreased by 158 microns ($p < 0.001$) compared with baseline. No drug-related adverse events were observed.

CONCLUSION

The improvements in VA and OCT measurements observed by Month 3 were maintained through Month 7 using an OCT-guided variable dosing regimen. These visual acuity results are very similar to the results observed in the Phase III trials at 7 months. One year results will be discussed. Continued follow-up is planned for 2 years.

* Financial interest disclosed