

Open-label, Multicenter, Phase II Study Assessing the Safety and Efficacy of Same-day Verteporfin and Liquid Ranibizumab 0.5mg (PROTECT Study)

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PURPOSE

To evaluate the safety and explore the efficacy of same-day administration of verteporfin and intravitreal injection of liquid ranibizumab 0.5mg.

METHODS

PROTECT is an open label, multicenter, Phase II, 9 month study, in patients with predominantly classic (n=13) or occult (n=19), subfoveal CNV secondary to AMD. Verteporfin was administered at baseline and then at month 3, 6 and 9 at investigator discretion. Ranibizumab 0.5mg was administered at baseline within 1h after verteporfin therapy, and then every month for 3 months. The primary study endpoint was the incidence of severe vision loss (≥ 30 letters loss in BCVA within 14 days of treatment and persisting >14 days). Secondary endpoints included effect on BCVA and lesion leakage. Safety was assessed using BCVA measurements, ophthalmic examinations, and adverse event monitoring.

RESULTS

No incidence of severe or moderate vision loss due to ocular inflammation was observed in any of the patients. Mean BCVA improved by 4.5 letters, and 10% of patients gained >15 letters at 1 month. Recurrent leakage was inhibited in 95% of patients at 1 month. The 4 month data is currently being analyzed and will be discussed in the presentation. Same-day administration of verteporfin plus ranibizumab 0.5mg appears to be safe and well tolerated. No new safety concerns above those identified for the individual monotherapies were observed.

CONCLUSION

Same-day verteporfin plus ranibizumab 0.5mg provided improvements in mean BCVA, inhibited recurrent leakage and was not associated with severe vision loss. These data support the rationale for verteporfin plus ranibizumab in combination therapy as an appropriate regimen for neovascular AMD.