

Six-month Results of a Randomized, Double-masked, Controlled Trial of Intravitreal Triamcinolone as an Adjunct to Photodynamic Therapy in Predominantly Classic Neovascular Age-related Macular Degeneration: The Canadian RETINA Study

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PURPOSE

To compare safety data and ETDRS visual acuity outcomes data for one-hundred subjects with predominantly classic (PC) choroidal neovascularization who were randomized to intravitreal triamcinolone (4mg) or sham injection as an adjunct to photodynamic therapy. Data will be presented from the planned, month-6 DSMC safety analysis.

METHODS

Subjects were randomized in double-masked fashion to intravitreal triamcinolone or sham injection (1:1 ratio) following photodynamic therapy at 3 month intervals. The CRTG virtual reading centre was used to confirm lesion eligibility prior to randomization. Best-corrected ETDRS visual acuities were compared between groups. The study was conducted according to GCP guidelines.

RESULTS

There was no difference between groups for severe adverse events. Adverse events were more common in the treatment group, but only for the known side effects of intravitreal triamcinolone. Visual results and number of retreatments favoured the combination therapy group.

CONCLUSION

The treatment of PC neovascular AMD with photodynamic therapy and intravitreal triamcinolone did not demonstrate any unexpected adverse or serious adverse events compared to photodynamic therapy alone. Exploratory data suggest an early therapeutic benefit with combination therapy. One-year data for the full cohort will be available in early 2007.

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