

VEGF inhibition study in ocular neovascularization (vision): Outcomes from the phase II/III Macugen pivotal trials

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Purpose:

To evaluate the safety and effectiveness of Macugen in the treatment of exudative AMD.

Methods:

Two phase II/III randomized, double masked, multicentered trials were conducted to study the effect of pegatanib sodium (Macugen) injected intravitreally versus sham injection every six weeks, in eyes with wet AMD of all sub-types. The primary endpoint was the percent of patient eyes losing less than 15 letters of visual acuity by 54 weeks. Adverse events were also recorded and analyzed. Patient eyes were evaluated by fluorescein angiography during the trial, and in part for ethical reasons, investigators were allowed to treat eyes with Verteporfin photodynamic thereapy if the eyes met the indications as stated on that product's label.

Results:

1186 patients were included in the analyses and were randomized evenly accross the treatment and sham groups. The primary endpoint was met with statistical significance for all doses in the combined analysis, and Macugen was beneficial for all lesion subtypes. At the 0.3 mg dose, 70 % lost fewer than 15 letters of visual acuity by week 54, compared to 55 % in the sham treated group (P = 0.0001).The treatment effect was independent of any PDT usage. Macugen was well tolerated systemically with no serious adverse events attributed to study drug.

Conclusion:

Macugen appears to be a safe and effective treatment choice for all the subtypes of wet AMD, and is the first effective biological treatment for this disease.

Take-home message:

Wet AMD treatment is undergoing a revolution, with more effective biological treatments coming available for ourpatients.The AMD management paradigm has shifted with the introduction of such an approach.