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ORIGINAL ARTICLE | VOLUME 145, ISSUE 2, P239-248 E5, FEBRUARY 2008

Randomized, Double-Masked, Sham-Controlled Trial of Ranibizumab for Neovascular Age-related Macular Degeneration: PIER Study Year 1

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Published: December 03, 2007 • DOI: <https://doi.org/10.1016/j.ajo.2007.10.004>

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Purpose

To evaluate the efficacy and safety of ranibizumab administered monthly for three months and then quarterly in patients with subfoveal choroidal neovascularization (CNV) secondary to age-related macular degeneration (AMD).

Design

Phase IIIb, multicenter, randomized, double-masked, sham injection-controlled trial in patients with predominantly or minimally classic or occult with no classic CNV lesions.

Methods

Patients were randomized 1:1:1 to 0.3 mg ranibizumab (n = 60), 0.5 mg ranibizumab (n = 61), or sham (n = 63) treatment groups. The primary efficacy endpoint was mean change from baseline visual acuity (VA) at month 12.

Results

Mean changes from baseline VA at 12 months were -16.3, -1.6, and -0.2 letters for the sham, 0.3 mg, and 0.5 mg groups, respectively ($P \leq .0001$, each ranibizumab dose vs sham). Ranibizumab arrested CNV growth and reduced leakage from CNV. However, the treatment effect declined in the ranibizumab groups during quarterly dosing (e.g., at three months the mean changes from baseline VA had been gains of 2.9 and 4.3 letters for the 0.3 mg and 0.5 mg doses, respectively). Results of subgroups analyses of mean change from baseline VA at 12 months by baseline age, VA, and lesion characteristics were consistent with the overall results. Few serious ocular or nonocular adverse events occurred in any group.

Conclusions

Ranibizumab administered monthly for three months and then quarterly provided significant VA benefit to patients with AMD-related subfoveal CNV and was well tolerated. The incidence of serious ocular or nonocular adverse events was low.

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References

1. Rosenfeld P.J. • Brown D.M. • Heier J.S. • et al.
Ranibizumab for neovascular age-related macular degeneration.
N Engl J Med. 2006; **355**: 1419-1431

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Biocon Exhibit 1023 Page 1

2.

Brown D.M. • Kaiser P.K. • Michels M. • et al.

Ranibizumab versus verteporfin for neovascular age-related macular degeneration.

N Engl J Med. 2006; **355**: 1432-1444

View in Article ^

Scopus (2982) • PubMed • Crossref • Google Scholar

3.

Heier J.S. • Antoszyk A.N. • Pavan P.R. • et al.

Ranibizumab for treatment of neovascular age-related macular degeneration: a phase I/II multicenter, controlled, multidose study.

Ophthalmology. 2006; **113**: 633-642

View in Article ^

Scopus (353) • PubMed • Abstract • Full Text • Full Text PDF • Google Scholar

4.

Rosenfeld P.J. • Heier J.S. • Hantsbarger G. • Shams N.

Tolerability and efficacy of multiple escalating doses of ranibizumab (Lucentis) for neovascular age-related macular degeneration.

Ophthalmology. 2006; **113**: 623-632

View in Article ^

Scopus (168) • PubMed • Abstract • Full Text • Full Text PDF • Google Scholar

5.

Hochberg Y.

A sharper Bonferroni procedure for multiple tests of significance.

Biometrika. 1988; **75**: 800-802

View in Article ^

Scopus (3737) • Crossref • Google Scholar

6.

Photodynamic therapy of subfoveal choroidal neovascularization in age-related macular degeneration with verteporfin: one-year results of two randomized clinical trials—TAP report 1.

Arch Ophthalmol. 1999; **117**: 1329-1345

View in Article ^

Scopus (1738) • PubMed • Crossref • Google Scholar

7.

Photodynamic therapy of subfoveal choroidal neovascularization in pathologic myopia with verteporfin.

Ophthalmology. 2001; **108**: 841-852

View in Article ^

Scopus (462) • PubMed • Abstract • Full Text • Full Text PDF • Google Scholar

8.

Visudyne. Novartis Pharmaceuticals Corp, East Hanover, New Jersey2005 ([package insert])

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Google Scholar

9.

Collaborative overview of randomized trials of antiplatelet therapy—I: Prevention of death, myocardial infarction, and stroke by prolonged antiplatelet therapy in various categories of patients.

BMJ. 1994; **308**: 81-106

View in Article ^

Scopus (708) • PubMed • Crossref • Google Scholar

10.

Fung A.E. • Lalwani G.A. • Rosenfeld P.J. • et al.

An optical coherence tomography-guided, variable dosing regimen with intravitreal ranibizumab (Lucentis) for neovascular age-related macular degeneration.

Am J Ophthalmol. 2007; **143**: 566-583

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Scopus (868) • PubMed • Abstract • Full Text • Full Text PDF • Google Scholar

Biography



Carl D. Regillo received his medical degree from Harvard and performed both his ophthalmology residency and vitreoretinal fellowship at Wills Eye Institute, Philadelphia, Pennsylvania. He is a prior Heed fellow and recipient of the American Academy of Ophthalmology Achievement and Senior Achievement Awards. Dr Regillo is currently the Director of the Wills Clinical Retina Research Unit, Professor of Ophthalmology at Thomas Jefferson University, and Chairman of the Academy Retina section of the Basic and Clinical Science Course.

Article info

Publication history

Published online: December 03, 2007

Accepted: October 5, 2007

Footnotes

Supplemental Material available at [AJO.com](#).

Identification

DOI: <https://doi.org/10.1016/j.ajo.2007.10.004>

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