# PIER (2008) and EXCITE (2011) studies



## **Objective**

To compare the efficacy and safety of quarterly and monthly ranibizumab injections in patients with exudative age-related macular degeneration (AMD)

## Methods

Design: Double-blinded RCT

**Sample Size:** N = 184, N = 293

Patients with subfoveal CNV secondary to AMD

#### **Treatment Groups:**

PIER: Ranibizumab injections monthly for 3 months followed by quarterly for 9 months vs. Sham

 0.3 mg (N=60), 0.5 mg (N=61), sham treatment (N=63)

EXCITE: Ranibizumab injections monthly for 3 months followed by monthly or quarterly for 9 months

 0.3 mg monthly (N=101), 0.3 mg quarterly (N=104), 0.5 mg quarterly (N=88)

#### **Outcome Measures:**

 Mean change in best-corrected visual acuity (BCVA)

### Results

**Point 1:** PIER - Quarterly treatment was better than sham, but did not maintain initially gained VA

- At 12 months, the sham treated group lost a mean of 16.3 letters while quarterly dosed groups lost a mean of 1.6 letters (0.3 mg group) or 0.2 letters (0.5 mg group) from baseline VA
- After an initial gain in VA from month 1-3, there was mean of 4.5 letter decline in VA in both ranibizumab groups between months 3-12

**Point 2:** EXCITE - Monthly treatment showed significantly greater improvement in VA compared to quarterly treatment

- At 12 months, quarterly dosed groups improved by a mean of 4.9 (0.3 mg) and 3.8 (0.5 mg) letters, while the monthly dosed group improved by a mean of 8.3 letters (0.3 mg) from baseline VA
- Between months 3-12, the patients in the quarterly treatment groups lost a mean of 1.8 (0.3 mg) and 2.8 (0.5 mg) letters, while patients in the monthly treatment gained a mean of 0.8 letters.

TLDR: Monthly ranibizumab treatment is superior to quarterly treatment for visual acuity in patients with AMD-related subfoveal CNV

Regillo CD, Brown DM, Abraham P, et al. Randomized, Double-Masked, Sham-Controlled Trial of Ranibizumab for Neovascular Age-related Macular Degeneration: PIER Study Year 1. *American Journal of Ophthalmology*. 2008;145(2):239-248.e5. doi:https://doi.org/10.1016/j.ajo.2007.10.004

Schmidt-Erfurth U, Eldem B, Guymer R, et al. Efficacy and Safety of Monthly versus Quarterly Ranibizumab Treatment in Neovascular Age-related Macular Degeneration: The EXCITE Study. *Ophthalmology*. 2011;118(5):831-839. doi:https://doi.org/10.1016/j.ophtha.2010.09.004