Fluid Study

- **Purpose**: To test whether tolerating some subretinal fluid (SRF) in neovascular age-related macular degeneration (nAMD) patients treated with ranibizumab using a treat-and-extend (T&E) regimen results in similar visual acuity (VA) outcomes compared to treatment aimed at resolving all SRF.
- **Study Design**: Multicenter, randomized, 24-month, phase 4, single-masked, noninferiority clinical trial.
- **Participants**: Treatment-naïve patients with active subfoveal choroidal neovascularization (CNV).
- **Methods**:
  - Participants were randomized into two groups:
    - **Intensive Arm**: Aimed at resolving all SRF and intraretinal fluid (IRF).
    - **Relaxed Arm**: Aimed at resolving IRF only, tolerating SRF unless it exceeded 200 μm at the foveal center.
  - A 5-letter noninferiority margin was applied to the primary outcome.
- **Main Outcome Measures**:
  - Mean change in best-corrected VA (BCVA) from baseline to month 24.
  - Central subfield thickness.
  - Number of injections over 24 months.
- **Results**:
  - Of 349 participants randomized, 279 (79.9%) completed the study.
  - Mean BCVA change from baseline to month 24:
    - Intensive group: +3.0 letters (SD, 16.3 letters).
    - Relaxed group: +2.6 letters (SD, 16.3 letters).
    - Noninferiority of the relaxed group was demonstrated (P = 0.99).
  - Similar proportions achieved:
    - 20/40 or better VA: 53.5% (intensive) vs. 56.6% (relaxed; P = 0.92).
    - 20/200 or worse VA: 8.7% (intensive) vs. 8.1% (relaxed; P = 0.52).

- Fewer injections in the relaxed group (mean, 15.8; SD, 5.9) compared to the intensive group (mean, 17; SD, 6.5; P = 0.001).
- Significantly more participants in the intensive group never extended beyond 4-week intervals (13.5%) compared to the relaxed group (2.8%; P = 0.003).
- More participants in the relaxed group extended to and maintained 12-week intervals (29.6%) compared to the intensive group (15.0%; P = 0.005).
- **Conclusions**: Tolerating some SRF in patients treated with ranibizumab using a T&E protocol resulted in comparable VA outcomes with fewer injections compared to aiming for complete resolution of SRF. This suggests that a more relaxed approach may be effective while reducing treatment burden.

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