Clinical Study - Statistical Methods

Investigator Initiated Interventional Study of Subjects With Diabetic Macular Edema Treated With Intravitreal Aflibercept Injection Previously Treated With Other Anti-VEGF Agents.

SWAP-TWO Study

NCT: 02559180

September 18, 2016

Statistical Analysis

Demography and Baseline Characteristics

Demographic and baseline characteristics were summarized descriptively by treatment group. Continuous variables were summarized with mean, median, standard deviation, minimum, and maximum. Categorical variables were summarized with frequency and percentage.

Outcome Measures

The primary outcome of the study was the mean absolute change from baseline CST at month 12 as measured by SD-OCT (defined as the average thickness within the central 1 mm subfield).

Secondary outcome variables include the following:

- The mean change from baseline in best-corrected visual acuity (BCVA) score at month 6,12, and 24
- Change in macular OCT perfusion at month 6,12, and 24 by OCT angiography
- The diabetic retinopathy severity change from baseline at month 6,12, and 24 as measured by the simplified ETDRS scale.
- Presence of microaneurysm and capillary dropout on OCT angiography at month 6,12, and 24 by OCT angiography
- The percentage of patients that were anatomically 'dry' by SDOCT at month 6,12, and 24
- The percentage of participants who gained or lost 5, 10, and 15 letters or more of vision at month 6,12, and 24
- The percentage of patients that are 20/40 or better at month 6,12, and 24
- The percentage of patients that are 20/200 or worse at month 6,12, and 24
- The incidence and severity of ocular and non-ocular adverse events (AEs) and serious AEs.

Safety Analyses

Safety assessments of both ocular and systemic events were conducted at each study visit. The AEs were categorized according to severity (mild, moderate, or severe) and possible or known relationship to the study drug.

Analysis

- Incidence and severity of ocular and non-ocular adverse events (AEs) and serious AEs

Statistical Methods

The study variables were summarized using standard descriptive statistics and normality of measures using the Shapiro–Wilk test, and distributed comparisons with and between groups were performed using two-sided paired t-tests. Where appropriate, sensitivity analyses using nonparametric Wilcoxon signed rank tests were also performed. Analyses were performed using SAS software (V.9.2; Cary, North Carolina, USA). A significance level of 0.05 was assumed for all tests. Missing data was accounted for using a linear mixed effect model.