

MATERIALS AND METHODS

Lp(a) levels measured after mipomersen treatment were compared with those of placebo. Lp(a) was measured using an isoform independent assay (MedPace, Siemens, BN™ II System) validated against a standard reference calibrator from the Northwest Lipid Research Clinic¹, as described in each trial.²⁻⁵

Statistics

Analyses were based on pooled data from the 4 phase 3 trials using the full analysis set (all randomized patients who received at least 1 injection of study drug and had a valid baseline with at least 1 post-baseline lipid assessment). Between-group differences in the mean percent change from baseline in Lp(a) at the primary efficacy timepoint (PET) were compared using a mixed model with a fixed effect for treatment and a random effect for study. PET was defined as date of the efficacy assessment closest to 14 days beyond the last study medication date. Spearman correlations analyses were conducted between percent change from baseline in Lp(a), LDL-C and apoB. All analyses were done using SAS (version 9.2).

References

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