A Randomized Trial Comparing the Efficacy and Safety of Intravitreal Triamcinolone With Observation to Treat Vision Loss Associated With Macular Edema Secondary to Central Retinal Vein Occlusion

The Standard Care vs Corticosteroid for Retinal Vein Occlusion (SCORE) Study Report 5

The SCORE Study Research Group

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eTable. Sensitivity Analyses to Assess Consistency of Primary Efficacy Results of the SCORE-CRVO Trial

Method	Results
LOCF	
Explanation	Repeated the primary analysis using LOCF for dropouts before 12 mo
Time period	12 mo
Result	Both triamcinolone acetonide groups were similar with respect to the primary efficacy outcome and significantly better than the observation group
Note	Within the 3 study groups, early visual acuity correlated highly with 12-mo visual acuity, so LOCF seems appropriate
Per protocol analysis	
Explanation	Repeated primary analysis including only study eyes with 12-mo visual acuity data and excluding participants who, before 12 mo, received an alternative treatment (ie, treatment crossovers) or a nonprotocol treatment, did not meet the eligibility criteria, or did not receive the treatment assigned at randomization
Time period	12 mo
Result	Both triamcinolone groups were similar with respect to the primary efficacy outcome and significantly better than the observation group
"Triamcinolone worst:" extreme-value scenario	
Explanation	Repeated primary analysis, except that all missing cases in the triamcinolone groups were assumed to be failures, while all missing cases in the observation group were assumed to be successes; this provides the minimum possible estimate of the treatment effect that is consistent with the observed data
Time period	12 mo
Result	Nonsignificant treatment effect; however, a nonsignificant treatment effect for triamcinolone is unlikely (see Cook-DeMets and Diggle tests)
Cook-DeMets test[1]	
Explanation	A test for treatment effect in which the *P* value depends not only on the observed data, but also on the assumptions the investigator makes about the extent of missing data in the treatment and control arms of the trial
Time period	12 and 24 mo
Result	For the range of parameters investigated, to assume that intravitreal triamcinolone (1-mg and 4-mg doses combined) was not superior to observation, one must assume that at least 5 times as many successes as failures are missing in the observation group, and that this ratio is much smaller in the triamcinolone groups
Diggle test[2]	
Explanation	Compared change from baseline in visual acuity of dropouts just before dropout with change from baseline in visual acuity at matching visits of those in the same treatment arm who subsequently stayed in study
Time period	12 mo
Result	No significant difference between dropouts and those who stayed in study
Note	In the 3 study groups, early visual acuity changes from baseline correlated highly with 12-mo visual acuity changes from baseline, so that the Diggle test suggests that dropouts were similar to those who stayed in with respect to primary outcome
Log-rank tests	
Explanation	Compared treatment groups with respect to dropout rates
Time period	12 and 24 mo
Result	No significant difference among treatment groups

Abbreviations: CRVO, central retinal vein occlusion; LOCF, last observation carried forward; SCORE, Standard Care vs Corticosteroid for Retinal Vein Occlusion (study).

REFERENCES

1. Cook YD, DeMets DL. *Introduction to Statistical Methods for Clinical Trials*. Boca Raton, FL: Chapman & Hall; 2008:356-358.
2. Diggle PJ. Testing for random dropouts in repeated measurement data. *Biometrics*. 1989;45:1255-1258.