U.S. Multicenter Trial of Efficacy and Tolerability of a Combined Compounded OMNI Formulation for Topical Prophylaxis After Laser Vision Correction

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Methods

- **Purpose:** To demonstrate non-inferiority to current regimen of multi-drug therapy in the context of laser-assisted in-situ keratomileusis (LASIK) population
- **Study Design:** Randomized 1:1, investigator masked, prospective, multi-center study of 101 refractive surgical eyes that underwent LASIK

Combination Drop Group OMNI

- Prednisolone Phosphate, 1% Gatifloxacin Ophthalmic Solution 0.5%, QID x 1 week

Multiple Drops Group

- Prednisolone Acetate* 1% QID x 1 week
- Gatifloxacin Ophthalmic Solution 0.5% QID x 1 week**

*Brand name Pred Forte, **Brand name Zymaxid

Primary Endpoint:

- Non-inferiority of the prevention of infection and inflammation over 1 month as assessed by upper bound of 2-sided 95% confidence interval for the between-group difference in mean change from baseline
- Analysis of covariance, ANCOVA, was used to analyze continuous measures, with fixed effects for treatment and investigative site, and baseline as a continuous covariate
- No adjustment made to p-values due to multiple comparisons

Secondary Endpoint:

- Refractive Outcomes, and clinical biomicroscopic examination. i.e. Corneal staining, and change in IOP.

AC Cell

		Control (N=52)	IP (N=49)
Screening	None >0	49 (100%) 0	52 (100%) 0
Day 1	None >0	49 (100%) 0	51 (100%) 0Z
Day 7	None >0	47 (100%) 0	49 (100%) 0
Day 30	None >0	46 (100%) 0	51 (100%) 0

AC Flare

		Control (N=48)	IP (N=52)
Screening	None 0.5 >0.5	48 (98%) 1 (2%) 0	52 (100%) 0
Day 1	None >0	49(100%) 0	51 (100%) 0
Day 7	None >0	47(100%) 0	49 (100%) 0
Day 30	None >0	46 (100%) 0	51 (100%) 0

Total Corneal Staining

		Control	IP	IP-Control	P
Day 1	N LS Mean (SE) 95% CI LS Mean (95% CI)	49 0.2 (0.11) (0.0, 0.4)	51 0.3 (0.10) (0.1, 0.5)	0.1 (-0.2, 0.4)	0.495
Day 7	N LS Mean (SE) 95% CI LS Mean (95% CI)	47 0.2 (0.16) (-0.1, 0.6)	49 0.4 (0.15) (0.1, 0.7)	0.1 (-0.3, 0.6)	0.525
Day 30	N LS Mean (SE) 95% CI LS Mean (95% CI)	46 0.2 (0.11) (0.0, 0.4)	51 0.0 (0.10) (-0.2, 0.2)	-0.2 (-0.5, 0.1)	0.262

*Wilcoxon Rank Sum test

IOP Change from Baseline

		Control	IP	IP - Control	P
Day 1	N LS Mean (SE) 95% CI LS Mean (95% CI)	11 -1.0 (0.97) (-3.1, 1.1)	6 -1.6 (0.95) (-3.7, 0.5)	-0.6 (-2.7, 1.5)	0.555
Day 7	N LS Mean (SE) 95% CI LS Mean (95% CI)	14 -2.2 (0.57) (-3.4, -1.1)	15 -1.6 (0.40) (-2.4, -0.7)	0.6 (-0.7, 2.0)	0.322
Day 30	N LS Mean (SE) 95% CI LS Mean (95% CI)	46 -1.0 (0.25) (-1.5, -0.5)	16 -1.7 (0.38) (-2.4, -0.9)	-0.6 (-1.5, 0.2)	0.138

*Wilcoxon Rank Sum test

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Results

- Study eye was defined as the eye with the highest total corneal staining score at the screening visit (baseline) and was used for analyses
- No significant differences between IP and Control at any visit as measured by AC cell, AC flare, and change from baseline in IOP, corneal staining, and visual acuity in the study eye
- Corneal Staining: upper limit of 95% CI was <0.2 at Day 30 demonstrating non-inferiority of IP to Control on this measure
- Mean decreases from baseline to Day 30 in Corneal Staining and IOP were greater in the IP group
- Changes from baseline in visual acuity were similar between IP and Control
- All patients scored 0 for AC cell and AC flare at Day 30
- There was no post-operative complication in either group
- There was no significant post-operative discomfort in either group at all time periods

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