Intraocular Pressure Reduction with NCX 470 versus Latanoprost Across the Spectrum of Baseline Intraocular Pressures

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PURPOSE

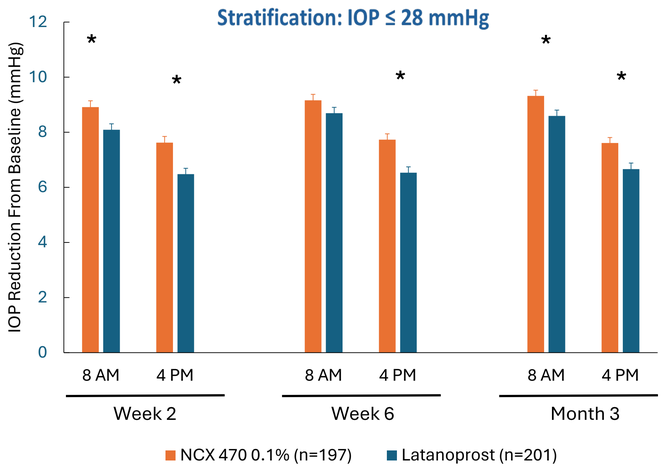
Compare the intraocular pressure (IOP) reduction from baseline with NCX 470 0.1% QD versus latanoprost 0.005% QD as a function of baseline IOP in subjects with open-angle glaucoma (OAG) or ocular hypertension (OHT).

METHODS

- An analysis of the intent-to-treat population (N=661) of the Mont Blanc clinical trial.
- IOP eligibility criteria included unmedicated IOP ≥26 mmHg at 8AM, ≥24 mmHg at 10AM, and ≥22 mmHg at 4PM in the study eye.
- The NCX 470 and latanoprost groups were stratified by mean baseline IOP at 2 eligibility visits into 2 groups:
  - Baseline IOP ≤28 mmHg or
  - Baseline IOP >28 mmHg
- IOP reductions (least squares means) were calculated at 8AM and 4PM separately as well as combined (diurnal IOP = mean of 8AM and 4PM time points) at weeks 2 and 6 and month 3 from analysis of covariance models.
- In a second analysis, IOP reduction (least squares mean) at 8AM at the month 3 visit was calculated for eyes randomized to NCX 470 (n=328) and latanoprost (n=333) across the spectrum of baseline IOPs.

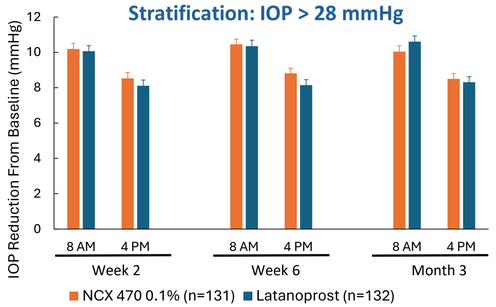
RESULTS

- In the ≤28 mmHg subgroup (n=398 eyes), mean IOP reductions with NCX 470 were numerically greater than with latanoprost at all 6 time points and were statistically significantly greater at 5 of 6 time points (0.73-1.20 mmHg; p≤0.0136).
- In this group, mean diurnal IOP reductions were statistically significantly greater with NCX 470 versus latanoprost at weeks 2 and 6 and month 3 (0.85-0.97 mmHg; p≤0.002).

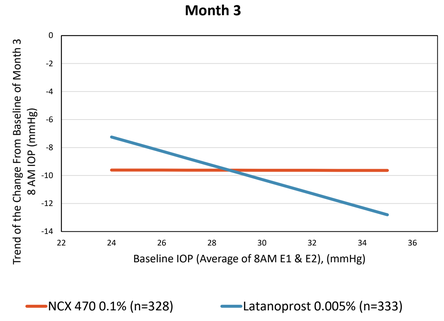


RESULTS

- In the >28 mmHg subgroup (n=263 eyes), mean IOP reductions and mean diurnal IOP reductions were similar between treatment groups at all time points.



- Mean IOP reduction at 8AM at month 3 was consistently ~9.5 mmHg across the entire range of baseline IOP (24-35 mmHg) with NCX 470 but varied between ~7-13 mmHg with latanoprost.



DISCUSSION

- NCX 470 provided consistent IOP reduction across the spectrum of baseline IOP while latanoprost IOP reduction was baseline IOP-dependent.
- In eyes with baseline IOP ≤28 mmHg, there was a statistically significantly greater IOP reduction from baseline for NCX 470 0.1% QD vs. latanoprost 0.005% QD at the majority of time points evaluated.

CONCLUSIONS

- NCX 470, a nitric oxide donating bimatoprost, demonstrated consistent IOP lowering independent of baseline IOP.
- For subjects with baseline IOP ≤ 28, NCX-470 0.1% demonstrated greater IOP lowering from baseline than latanoprost at all time points and was statistically superior at 5 of 6.

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