



**A MULTICENTRIC, DOUBLE BLIND, RANDOMIZED, ACTIVE CONTROL, PARALLEL GROUP, COMPARATIVE STUDY TO EVALUATE THE EFFICACY, SAFETY AND TOLERABILITY OF REBAMIPIDE OPHTHALMIC SUSPENSION 2.0% W/V VS. SODIUM HYALURONATE OPHTHALMIC SOLUTION 0.1% W/V FOR THE TREATMENT OF PATIENTS WITH DRY EYE.**

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## BACKGROUND

The study was designed to evaluate the efficacy, safety and tolerability of Rebamipide Ophthalmic Suspension 2.0% w/v (Arm A) Vs. Sodium Hyaluronate Ophthalmic Solution 0.1% w/v (Arm B) in Subjects Suffering from Dry Eye. The main objective of the study was to compare subjects-perceived relief from the symptoms of foreign body sensation, dryness, photophobia, eye pain, blurred vision.

## METHOD

It was a comparative, randomized, double blind, parallel group, active control, multi-centric clinical trial conducted in 08 centers across India in subjects with signs and symptoms of dry eye. The recruitment has been start from Jun 09, 2015 to Mar 16, 2016. Total 236 patient (aged 18 – 65 years) were randomized in the ratio of 1:1 in both arms.

All the subjects were advised to instil one drop four times daily in affected eye of either Rebamipide Ophthalmic Suspension 2.0% w/v or Sodium Hyaluronate Ophthalmic Solution 0.1% w/v as per randomization. The treatment continued for 168 days with periodic follow-up on 28<sup>th</sup>, 56<sup>th</sup>, 84<sup>th</sup>, 112<sup>th</sup>, 140<sup>th</sup> and 168<sup>th</sup> days from start of treatment.

## RESULTS

The current study showed the Mean change in Fluorescein Corneal staining score from baseline to visit 7 for Rebamipide Ophthalmic Suspension 2.0% w/v and Sodium Hyaluronate Ophthalmic Solution 0.1% w/v as – 2.15 and – 1.9 respectively. There were 15 clinical adverse events reported (Rebamipide: 06, Sodium Hyaluronate: 09) which were mild in nature.

## CONCLUSION

Rebamipide Ophthalmic Suspension 2.0% w/v has higher efficacy of improving clinical features of dry eye when compared with Sodium Hyaluronate Ophthalmic Solution 0.1% w/v and as safe as Sodium Hyaluronate Ophthalmic Solution 0.1% w/v.

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