

## **A Combination Povidone-Iodine 0.4% Dexamethasone 0.1% Ophthalmic Suspension in the Treatment of Adenoviral Conjunctivitis**

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**Purpose:** The objective of this pilot study was to determine the preliminary efficacy of a novel ophthalmic suspension containing a combination of povidone-iodine 0.4% and dexamethasone 0.1% in the treatment of adenoviral conjunctivitis.

**Design:** Prospective, open-label, single-armed, Phase II clinical trial in humans.

**Methods:** Eligible patients with the clinical signs and symptoms of acute conjunctivitis who tested positive for adenoviral antigen by RPS Adeno Detector™ were enrolled in a single treatment arm consisting of a combination povidone-iodine 0.4% / dexamethasone 0.1% sterile ophthalmic suspension given 4 times daily for 5 days. RPS Adeno Detector™ testing was performed at baseline and at each follow-up visit along with ocular fluid sampling by conjunctival swabs. Subsequent analysis performed on all swabs included both adenoviral titer by quantitative polymerase chain reaction (qPCR) and cell culture with confirmatory immunofluorescence (CC-IFA). The primary endpoint was clinical resolution of conjunctival injection and discharge. Secondary measures included reduction of qPCR titers and eradication of infectious virus as determined by CC-IFA.

**Results:** A total of 9 eyes of 6 patients with clinical signs and symptoms of acute viral conjunctivitis and a positive RPS Adeno Detector™ test result were enrolled in the study. In 8/9 eyes enrolled in the study, clinical resolution was observed by Day 3 or Day 4. In 6/6 eyes with detectable adenovirus by qPCR, significant reduction in viral titer was seen by Day 3, Day 4 or Day 5. In 5/6 eyes with infectious virus confirmed by CC-IFA at enrollment, elimination of infectivity was achieved by Day 4 or Day 5.

**Conclusions:** A combination ophthalmic suspension containing povidone-iodine 0.4% and dexamethasone 0.1% may be a useful agent in the treatment of acute RPS Adeno Detector™ positive conjunctivitis. A further placebo-controlled study with a larger number of patients is warranted.