Introduction

Adenoviral conjunctivitis (Ad-Cs) is a highly contagious disease that can quickly spread through clinics, homes, schools and work places with significant morbidity.

There is no FDA-approved treatment for Ad-Cs; however, use of several off-label treatments have been reported, including a one-time administration of ophthalmic 5% povidone-iodine (PVP-I). In a 2013 survey of eye care practitioners, one-third of respondents reported using ophthalmic 5% PVP-I in the treatment of Ad-Cs.

The safety and tolerability of 5% ophthalmic PVP-I has not been systematically evaluated in eyes with AdCs. Therefore, it is important to evaluate the safety and tolerability of PVP-I in a double-masked randomized clinical trial with placebo control.

The Reducing Adenoviral Patient Infected Days (RAPID) study is a double-masked, randomized planning trial to estimate parameters for designing a definitive clinical trial of the safety and efficacy of 5% PVP-I in the treatment of Ad-Cs.

Methods

Of 212 participants screened, 56 eligible participants with red eye symptoms 4 days and a positive adenoviral rapid immunoassay were randomized to a one-time administration of ophthalmic 5% PVP-I or preservative free artificial tears (AT).

Safety was assessed by corneal fluorescein staining (baseline, immediate post-administration and Day 1) and visual acuity (VA) (baseline and Day 1).

Tolerability was assessed using participant-rated overall ocular discomfort (baseline, immediate post-administration and on Day 1) and clinician-rated participant discomfort (immediately post-administration).

Results

In the 5% PVP-I group, corneal staining increased immediately post-administration but returned to baseline levels by Day 1 (Figure 1).

There was no change in VA between baseline and Day 1 in either 5% PVP-I or AT groups (p=0.87).

In the 5% PVP-I group, there was no change in participant-rated overall discomfort immediately post-administration (p=0.78) or on Day 1 (p=0.10), compared to baseline (Figure 2).

In the AT group, participant-reported overall discomfort was lower immediately post-administration but returned to baseline levels by Day 1 (Figure 2).

One adverse event was reported in the 5% PVP-I group on Day 1 that was classified as not related to treatment.

The unmasked clinician-rated overall patient discomfort was higher in the 5% PVP-I group (5.6 ± 2.9) compared to the AT group (2.5 ± 2.7, p=0.0002).

Figure 1. Total corneal fluorescein staining.

Mean corneal staining was significantly increased immediately post-administration in the 5% PVP-I group. There was no difference in mean staining in the AT group.

Figure 2. Participant-rated overall ocular discomfort

There was no difference in baseline and immediate post-administration overall discomfort in the 5% PVP-I group. In the AT group, overall discomfort immediately post-administration was lower than baseline rating. On Day 1, there was no difference in participant rated overall discomfort compared to baseline levels.

Discussion

For decades, PVP-I has been used as an ophthalmic surgical antiseptic; however, there are limited in vivo studies assessing patient tolerability to exposure in the context of Ad-Cs.

In this study, by Day 1, corneal staining was minimal and was comparable to levels previously reported in successful daily wear and extended wear contact lens patients. Participants had stable VA and were minimally symptomatic, providing evidence that supports the treatment with 5% PVP-I was safe in individuals with presumed Ad-Cs.

The results of this study demonstrate that although there is statistically significant corneal staining post-administration of 5% PVP-I, by day 1, corneal staining is equivalent to treatment with artificial tears alone.

References

1. Abelein M, AS. A guide to understanding adenovirus, the disease it causes and the best ways to treat these conditions. Review of Ophthalmology. 2020.

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Clinical Trial Registration: https://clinicaltrials.gov/ct2/show/NCT04722223

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