

Patient Safety Data Across Clinical Trials Using Suprachoroidal Injection of Triamcinolone Acetonide

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Presentation type:

All of the above

Presentation Topic:

Retinal Vascular Disease

Purpose:

Suprachoroidal injection of drugs for treatment of eye disease is a unique approach undergoing clinical development. Safety data from use of TA as monotherapy or in combination with intravitreal aflibercept will be reviewed. Efficacy data will provide further insight.

Methods:

Data from 30 patients from 2 clinical trials in noninfectious uveitis (NIU) including a phase 1/2 and a masked, randomized phase 2 will be included. Masked safety data from an ongoing 150-patient phase 3 trial in NIU may be included. One phase 2 randomized, masked, controlled trial with 46 patients in RVO where one arm received suprachoroidal CLS-TA with intravitreal aflibercept will also be presented.

Results:

In 3 trials, 30 NIU patients were dosed with suprachoroidal injections of TA, and 23 RVO patients were dosed with combinations of suprachoroidal TA and intravitreal aflibercept. No related SAEs have been reported; the most common AE (~33%) is eye pain at or near the time of procedure. In NIU patients, single AEs of conjunctival edema, conjunctival hemorrhage, dry eye and papillitis were reported. No increases in IOP have been seen in NIU patients. In the combination treatment in RVO, 2 events of conjunctival hemorrhage and several single AEs were observed. Two increases in IOP and 2 ocular hypertension cases were seen in RVO patients. All elevated IOP incidents were managed with topical drops. Mean improvements ranged from 9-13 ETDRS letters gained in NIU patients, and 19 letters gained in RVO patients. There are hints of durability when using suprachoroidal treatment; over 50% of patients in each of the 3 studies being discussed remained only on study drug at 6, 2 and 3-months following a single treatment of TA at baseline.

Conclusions:

Suprachoroidal TA is being evaluated as monotherapy in NIU patients or as combination therapy with aflibercept in RVO patients. Data from 53 patients in completed trials shows no unique AEs attributable to suprachoroidal drug, and a relatively unremarkable overall safety profile. Elevated IOP incidence is low (<10%) and consistent with the unique distribution of drug seen from animal models with sparing of the anterior chamber and lens. Evaluation from larger studies is ongoing and results will be useful to assess the potential for this treatment approach.

Presented Before:

No