Evaluating the True Rate of Recurrence of Non-Infectious Posterior Segment Uveitis Following Treatment with an Injectable Fluocinolone Acetonide Insert

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Purpose:
Systemic anti-inflammatory and immunosuppressive treatments used for non-ocular or fellow-eye inflammation can confound study-eye outcomes when evaluating intravitreal sustained-release injectable fluocinolone acetonide insert (FAi) treatment of non-infectious posterior segment uveitis (NIPU) of only one eye. This analysis characterizes the reasons for use of confounding systemic medications to determine the true recurrence rate following the FAi insert.

Methods:
This was a post-hoc analysis of a phase 3, 36-month study. Subjects with a > 1-year history of recurrent NIPU, who had experienced ≥ 2 separate recurrences requiring ≥ 3 months of systemic therapy or ≥ 2 intra- or periocular steroid injections were randomized to treatment with FAi (n=87) or sham (n=42) (clinicaltrials.gov NCT01694186). Treatment of underlying systemic disease or recurrent intraocular inflammation in either eye was at the investigator’s discretion. When possible, systemic therapy was used only if local therapy failed. We reviewed all cases of imputed recurrence due to the use of confounding systemic medications to better characterize the true observed rate of recurrence.

Results:
Overall, the reported uveitis recurrence rate was lower in the FAi treatment group (56%) compared to sham (93%) (p<0.001). In the FAi treatment group, 27/49 (55.1%) recurrences were imputed as the result of confounding systemic medication use, in contrast to 9/39 (23.1%) recurrences in the sham group. In 12 cases (10 FAi [20.4% of recurrences] and 2 sham [5.1% of recurrences]) there was sufficient evidence that the sole reason for designating the study eye a treatment failure was the use of a confounding systemic medication. Among these 12 cases, 7 (58.3%) were the result of systemic treatment of a non-ocular condition and 5 (41.7%) were the result of systemic treatment for fellow-eye inflammation.

Conclusions:
Over half of the recurrences in the 36-month phase 3 clinical trial were imputed as a result of confounding systemic medication use. The true rate of recurrence in study eyes treated with FAi is likely lower than the 56% that has been reported.