

Title: Suprachoroidal Triamcinolone for Sub-Tenon–Resistant, Non-Infectious Uveitic Macular Edema

Approval ID: 2024-234

Date: 1/6/2024

Study Protocol

Background:

Uveitis, or intraocular inflammation, is a complex condition that affects key internal ocular structures such as the retina, choroid, vitreous, iris, and ciliary body. If not properly managed, it can lead to serious visual impairment. The management of sub-Tenon Triamcinolone acetonide STA-resistant uveitic macular edema remains a significant clinical challenge that warrants further investigation.

Design: Prospective, single-arm, open-label (no blinding)

Study Start Date: *September 01, 2024*

Setting: Single center

Objectives

- **Primary:** Proportion of eyes with visual acuity improvement ≥ 2 lines at Month 3.
- **Secondary:** Proportion of eyes with $\geq 20\%$ reduction in central macular thickness (CMT) at Month 3 vs baseline.

Participants

Inclusion:

- Non-infectious uveitis complicated by macular edema
- Uveitic macular edema <4 months' duration
- Macular edema persisting despite absence of intra-ocular inflammation
- No response to posterior sub-Tenon triamcinolone acetonide injections

Exclusion:

- Epiretinal membrane-associated macular edema
- Age <18 years

Intervention

- Suprachoroidal triamcinolone acetonide 4 mg/0.1 mL injection
- Performed in an operating room under sterile conditions, superotemporal (4–4.5 mm from limbus; Nozik approach) using a custom depth-limited 27G needle system (non-proprietary).

Assessments & Visits

- Baseline, Month 1, Month 3: Best-corrected visual acuity and OCT-derived CMT.
- (No predefined IOP rules; no safety or rescue analyses.)

Ethics

- **Ethical approval:** University of Baghdad, College of Medicine.

Statistical Analysis Plan

- Software: IBM SPSS Statistics v24
- Data display: Continuous variables as mean \pm SD; categorical as frequency (percentage).
- Primary endpoint: Proportion with ≥ 2 -line VA improvement at Month 3; report n (%) (two-sided $p < 0.05$ considered significant).
- Secondary endpoint: Proportion with $\geq 20\%$ CMT reduction at Month 3; report n (%). For changes in CMT across time points, apply repeated-measures tests (repeated-measures ANOVA) as appropriate.

References:

- 1- 1. Asghar MA, Tang S, Wong LP, Yang P, Zhao Q. "Infectious uveitis: a comprehensive systematic review of emerging trends and molecular pathogenesis using network analysis". J Ophthalmic Inflamm Infect. 2024 Nov 20;14(1):60. doi: 10.1186/s12348-024-00444-8.
- 2- 5. Al-Ani, H.H., Sims, J.L. & Niederer, R.L. Long term complications and vision loss in HLA-B27 uveitis. Eye 2023; 37, 1673–1677. <https://doi.org/10.1038/s41433-022-02216-x>