

European Society of Ophthalmology



Name: SARAH TOUHAMI
European Leadership Development Program Class of 2023-2025

Project Abstract

Title of Project: STEROID STEP THERAPY IN DIABETIC MACULAR EDEMA

Purpose: In eyes with diabetic macular edema (DME), the relative efficacy of intravitreal injections of dexamethasone as monotherapy, compared with subtenon injections of triamcinolone acetonide first with a switch to dexamethasone if the eye condition does not improve sufficiently (step therapy), is unclear. The purpose is to compare the two approaches with the goal of reducing the costs.

Methods: Prospective randomized trial comparing dexamethasone implant (DEXi) monotherapy and a step therapy of subtenon injections of triamcinolone acetonide (STTA) followed by DEXi in case of anatomic inefficacy, as treatments of DME. Best corrected visual acuity, central macular thickness, and intraocular pressure will be measured at baseline, before and 2 months after each injection, then on a 2 monthly-basis until month 24. Drugs will be administered at randomization and thereafter according to the prespecified retreatment protocol. Beginning at 16 weeks, eyes in the STTA-first group will be switched to DEXi if protocol-specified criteria are met. The primary outcome will be the mean change in visual acuity over the 2-year trial period. Retinal central subfield thickness, visual acuity at 2 years and safety data will also be assessed along with the costs of treatments and medical visits.

Results: This is an ongoing project.

Conclusion:

We expect this “step therapy” approach to be comparable to the conventional management with DEXi monotherapy in terms of visual acuity gains. We also expect it to be superior in terms of costs. The final results will allow to provide cost-effective recommendations for future practice.