

**Dexamethasone Intravitreal Implant (0.7mg) for
the Treatment of Persistent Diabetic Macular
Edema Following Intravitreal Anti-Vascular
Endothelial Growth Factor Therapy (DIME Trial)**

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STUDY DESIGN

DESCRIPTION OF THE STUDY

This is a pilot study of dexamethasone intravitreal implant (0.7mg) in subjects with clinical, angiographic and spectral-domain optical coherence tomography (SDOCT) evidence of persistent diabetic macular edema following intravitreal anti-vascular endothelial growth factor (anti-vegf) treatment. Forty patients will be enrolled in this study.

Consented subjects will receive anti-vegf therapy (aflibercept, bevacizumab or ranibizumab) administered every 30 days (± 7 days) during the run-in phase at baseline, month 1, and month 2. Subjects will receive the same anti-vegf medication throughout the run-in phase. Subjects with less than 10% reduction or any increase in central 1mm subfield thickness (CST) compared to baseline values and CST is greater than 300 microns or subjects with any reduction in CST, but whose CST remains above 350 microns with concurrent and persistent DME as measured on SDOCT following the run-in phase, will be randomized 1:1 to receive either dexamethasone intravitreal implant (0.7mg) or continue on the same anti-vegf therapy.

Subjects randomized to dexamethasone intravitreal implant (0.7mg) will receive the initial treatment at Month 3 (visit 4) and Month 6 (visit 7) and are eligible to receive one additional dose at Month 9 (visit 10), Month 10 (visit 11) or Month 11 (visit 12) for persistent or recurrent macular edema documented on SDOCT. If dexamethasone intravitreal implant (0.7mg) is administered at Month 10 (visit 11) or Month 11 (visit 12) an additional safety study visit will be required at one to two months following Month 12 (visit 13). The investigator can withhold treatment with dexamethasone intravitreal implant (0.7mg) beginning at Month 9 if there is complete resolution of diabetic macular edema document on SDOCT.

Subjects randomized to continue on anti-vegf therapy will receive intravitreal anti-vegf injections at Month 3 (visit 4) Month 4 (visit 5) and Month 5 (visit 6). Beginning at Month 6 (visit 7), subjects who have received 6 intravitreal anti-vegf injections and continue to present with persistent diabetic macular edema defined as less than 10% reduction or any increase in CST compared to baseline values and CST is greater than 300 microns, will receive dexamethasone intravitreal implant (0.7mg) at Month 6 (visit 7) and Month 9 (visit 10). The follow-up period for all subjects will continue through 12 months from the baseline study visit.

The primary outcome endpoint is 9 months from randomization (Month 12 from day of enrollment). The total length of follow-up is 12 months. All subjects will make monthly visits for 12 months for evaluation of safety and efficacy. All subjects will have their first intravitreal injection at Baseline/Day 0 study visit. At subsequent visits, the subject will have a safety evaluation at the monthly scheduled follow-up visit prior to any intravitreal injection.

Statistical Analysis Plan

Mean change in CST and best corrected visual acuity (BCVA) will be assessed by an unpaired Student's t-test. Total number of injections in each arm will be given as a number.