Official Title of the study:

Effect of Dexamethasone on Reduction of Macular Thickness in Diabetic Patients, a Randomized Clinical Trial

NCT number

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Study Protocol:
Data from DME diagnosed volunteers was collected and analyzed at the Department of Ophthalmology, State University of Campinas (UNICAMP), Brazil between May 2016 and December 2017.
Inclusion criteria included: (1) aged 18 years or over; (2) diagnosis of Type 2 DM; (3) patients with pseudophakic eyes; (4) presence of clinically significant DME according to ETDRS guidelines; (5) best corrected visual acuity (BCVA) between 20/400 and 20/40; (5) central macular thickness (CMT) of >= 300 µm, measured by spectral domain optical coherence tomography (Spectralis® Heidelberg). If both eyes met eligibility criteria, the eye with worse BCVA at baseline was used as the study eye.
Exclusion criteria were: (1) any treatment of DME in the previous 4 months; (2) pan retinal photocoagulation (PRP) in the last 4 months or likelihood of necessity to undergo PRP during the next 6 months; (3) any ophthalmologic surgery performed in the last 4 months; (4) history of pars plana vitrectomy (PPV); (5) history of open-angle glaucoma or corticosteroid-induced elevated intraocular pressure that required antiglaucoma or anti-hypertensive ocular treatments; (6) intraocular pressure of >= 21 mmHg; (7) patients that refused to sign the informed consent form.
During the screening consultation, complete ophthalmic evaluation, including BCVA, slit-lamp biomicroscopy, applanation tonometry, fundus biomicroscopy, fluorescein angiography (Visucam NM/ FA Carl Zeiss; Carl Zeiss Meditec, California, USA) and SD-OCT (Spectralis; Heidelberg Engineering, Heidelberg, Germany) was performed. CMT was obtained through seven horizontal lines (30° x 5° area), centered on the fovea, with 1536 A scans per line at 240 µm intervals.
Patients were randomized via a 1:1:1 sequential allocation to receive 0.01 ml (40µg), 0.03 ml (120µg), or 0.05 ml (200µg) of the 4mg/ml dexamethasone solution during the primary study visit (baseline). In subsequent visits, at one, three, seven, 14, 21, and 28 days, analysis via BCVA, slit-lamp biomicroscopy, applanation tonometry, fundus biomicroscopy, and SD-OCT (Spectralis; Heidelberg Engineering, Heidelberg, Germany) was performed.
The current study used blocked randomization (3 groups with 9 members each); data was computer generated, and stored in a locked cabinet until the end of the study period. Patients, study personnel responsible for intravitreal injections and those responsible for collecting BCVA, IOP, OCT data were blinded as to the patient study assignment.

Statistical Analysis Plan:
Calculations based on effect size at 0.5 standard deviations of macular thickness between pre injection (baseline) and the 3rdday post injection indicated that a sample size consisting 27 subjects would be sufficient for detecting a difference of this magnitude with a power of 0.8 and a significance level of 0.05 (one-tailed).
In statistical analysis, continuous data were expressed as the mean ± standard deviation and range. Between-group differences of continuous variables were compared using Kruskal-Wallis 1-way ANOVA, Wilcoxon Signed Ranks Test or Mann–Whitney U test when appropriate, and categorical variables were compared using or Fisher – Freeman – Halton exact test. Analyses were performed using IBM SPSS Statistics version 20. Statistical significance was established when $p \leq 0.05$.