Effect of Phenytoin on the Ganglion Cell Layer in Patients with Optic Neuritis
NCT02939937
7/5/2019

Statistical Analysis plan:
The distribution of numerical data is tested for normality using the Shapiro-Wilk test. Descriptive statistics are calculated as the mean and standard deviation. Categorical variables are compared using the chi-square test. To evaluate the changes of thicknesses of different layers over 6 months, a repeated-measures, mixed-effects model is used. The dependent variables were the layer thicknesses, visual field, and visual acuity measured at 3 time points: baseline, one month, and 6 months. We report the amount of ganglion cell inner plexiform layer thickness changes at baseline, one month and six months between placebo and phenytoin group using linear mixed model. Multiple linear regression will be used to test a set of OCT variables (models) obtained at the onset of the study and after 1 month, to predict the visual acuity outcomes by month 6.