

REACT Study

Safety and Efficacy of Intravitreal Ranibizumab for Diabetic Macular Edema Previously Treated with Intravitreal Bevacizumab: A Randomized Dual-Arm Comparative Dosing Trial (Phase:1/2):

IND 120427

NCT01982435

Statistical Analysis Plan

11-07-2013

Measures for this study will be summarized using means, range and standard error of the means (SEM).

Two-sided paired t-tests and two-sided unpaired t-tests will respectively be conducted to analyze efficacy endpoints between study initiation to end, and between monthly and Treat and extend injection regimens. Patients who exit the study early can be accounted for by using a last observation carried forward approach. Chi-squared analysis will be used to assess significant differences in ophthalmic adverse event frequency. All analyses will be performed using GraphPad Prism 5 (GraphPad Software, La Jolla, California, USA) with a significance level of 0.05 being assumed for all tests