Early Feasibility Prospective Open-Label Study to Assess the Function of a Novel Pessary for the Non-Surgical Management of Pelvic Organ Prolapse

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Statistical Design and Power

Recognizing that formal statistical procedures and power analyses are not the main focus of an early feasibility trial for a medical device, a few points will be made about the choice of 15 subjects. As reported by Cundiff et al. (2007), of 57 women initially successfully fitted with the Gellhorn pessary, within a week 21 had to be refitted which is a short-term fitting failure rate of about 37%. A 95% confidence interval about this proportion using an exact binomial test ranges from 24% to 51%. We can record the number of short-term failures in our preliminary study and compare our rate to Cundiff et al. If 4 of 15 (27%) of our subjects or fewer have to be refit, we could reject the null hypothesis of a short-term failure rate of .51 or greater at $p < .05$. Or, from a power perspective, if our true short-term failure rate was 21% or lower, power would be .81 or higher to reject the null hypothesis that our true failure rate is 51% or greater. This would give us another perspective on how fitting our new pessary compares to fitting existing pessaries.