

Cover Page for Statistical Analysis Plan

Sponsor name:	Northwestern University
NCT number	NCT02678377
Sponsor trial ID:	STU00201249
Official title of study:	The SLIM Study: Sling and Botox® Injection for Mixed Urinary Incontinence
Document date:	21 October 2022

Statistical Analysis Plan

We based the sample size estimation off of previous studies assessing treatment of slings for mixed urinary incontinence and onabotulinumtoxinA injections for overactive bladder. A PGI-I response at 3 months postoperatively of “very much better” or “much better” was designated “improved.” Assuming 66% of women in the placebo group and 93% in the onabotulinumtoxinA group were “improved” based on overall PGI-I scores, 68 women (34 in each arm) were needed to show a significant difference with 80% power at 0.05 significance level. If we assumed a 15% dropout rate, we aimed to recruit 78 participants (39 in each arm). R 3.6.3 was used for statistical analysis of the deidentified data. Independent samples t test, Mann-Whitney, χ^2 , Wilcoxon signed rank sum statistical tests were used as appropriate.