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## Statistical Analysis Cover Page

### Study Protocol

ID: 2022P-000826

A Pilot Study to Assess Effects of Self-Administered Nitrous Oxide (SANO) on Urodynamic Study (UDS) Parameters

#### Please note:

In our original study protocol, we had based our sample size calculation on a study by Jeon et al. However, as the inter-class correlation was not reported in the study by Joen et al., using their study increases our risk of a type 2 error. In light of this, we performed a literature review of all studies comparing cystometric capacity on repeat cystometry to identify a study that also reports inter-subject correlation. Using the maximum cystometric capacity (MCC) by Broekhuis et al., with an interclass correlation coefficient of 0.86, the sample size calculation to detect clinically relevant a priori difference in 50mL with a power of 82% was 16 patients total. The resulting sample size is less than the amount recruited in our study (19), thus the risk of a type 2 error is less than 20%. The below statistical analysis reflects our updated design.

### *Outcomes*

An intention-to-treat analysis was performed on 19 participants. MCC was measured as the primary outcome. Secondary outcomes included patient-reported pain and anxiety measured at baseline and immediately before maximum capacity during each UDS run using the Visual Analog Scale for Pain (VAS-P; range 0-10) and the Visual Analog Scale for Anxiety (VAS-A; range 0-10).

### *Statistical Analysis*

Bivariate analyses were performed to compare UDS outcomes, pain and anxiety scores, and operator-reported outcomes during SANO and Oxygen runs. Paired Wilcoxon signed rank sum test and McNemar's chi-squared Tests were used for continuous and categorical variables, respectively. For two variables (Patient Responsiveness during UDS and Observed Patient Procedure Tolerance), there were no categorical responses for the treatment arms. Therefore, the substitution of zero with a value of 0.5 was used to satisfy the chi-squared conditions. Subgroup analysis was performed to compare key UDS outcomes between treatments for patients randomized to either Oxygen or SANO on the 1<sup>st</sup> run. Additionally, a sensitivity analysis was performed comparing UDS outcomes between treatment groups for the 1<sup>st</sup> UDS run only. An alpha of 0.05 and 95% confidence intervals (CI) were used as criteria for statistical significance. For continuous data, a pairwise version of the Hodges-Lehman Median Difference method was used to estimate a pseudo-median difference and corresponding 95% CI. Data were collected and stored using REDCap electronic data capture tools hosted at Beth Israel Deaconess Medical Center. Analyses were performed using Microsoft Excel (v16.66.1), R (v4.3.0), and SPSS (v29.0).