Pilot Study to Establish Safety and Ease of Use of a TauTona Pneumoperitoneum Assist Device (TPAD) for Laparoscopic Surgery

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Statistical Analysis Plan

Statistical Methods

For surgeon and patient questionnaire answers, a Wilcoxon test will be performed for each answer against a theoretical median of 4.0 (best). Since the insertion of the Veress needle should not significantly impact the final outcome of the entire laparoscopic procedure, analysis assumes that the theoretical median for each answer should be 4.0. Further, the standard of care is assumed to provide the current best care, so its theoretical median should be 4.0.

Determination of Sample Size

There were no statistically powered sample size requirements for this study. Based on the end points, the sample size of 15 for each group would be sufficient to determine bruising and the ability of the TPAD device to function as intended as compared to the control group.