

**PROSPECTIVE STUDY INVESTIGATING THE OPTIMAL DURATION OF INDWELLING URINARY CATHETER FOLLOWING INFRAPERITONEAL
COLORECTAL SURGERY AND ROLE OF POSTOPERATIVE ALPHA-BLOCKADE**

Protocol Number: Version 3 Date 11/30/2012

Lead Investigator: Phillip Fleshner, MD
Division of Colorectal Surgery
Cedars-Sinai Medical Center

Protocol No./ Title:	Prospective study investigating the optimal duration of indwelling urinary catheter following infraperitoneal colorectal surgery and role of postoperative alpha-blockade														
Statistical Analysis Plan:	<p>Determine the incidence of retention of two groups. A control group of 72 hours catheterization (Group 1) to 24 hours catheterization plus medication (Group 2) to potentially reduce retention.</p> <p>Data Description: Non-inferiority study $p_A=0.15$, $p_B=0.15$, $d=0.15$ (tolerance). We would like to test 1) If Group 2 is non-inferior to Group 1 (2 is not worse than 1).</p> <p>Power Analysis and Sample Size Calculation:</p> <p>A sample size for 80% power is 71 per group. This would be a total of 142.</p> <p>Two group test of equivalence in proportions</p> <table data-bbox="510 1003 1432 1317"> <tr> <td>Test significance level, α (one-sided)</td> <td>0.050</td> </tr> <tr> <td>Standard proportion, p_S</td> <td>0.150</td> </tr> <tr> <td>Equivalence limit difference, $p_T - p_S, D_0$</td> <td>0.150</td> </tr> <tr> <td>Test expected proportion, p_T</td> <td>0.150</td> </tr> <tr> <td>Expected difference, $p_T - p_S, D_1$</td> <td>0.000</td> </tr> <tr> <td>Power (%)</td> <td>80</td> </tr> <tr> <td>n per group</td> <td>71</td> </tr> </table>	Test significance level, α (one-sided)	0.050	Standard proportion, p_S	0.150	Equivalence limit difference, $p_T - p_S, D_0$	0.150	Test expected proportion, p_T	0.150	Expected difference, $p_T - p_S, D_1$	0.000	Power (%)	80	n per group	71
Test significance level, α (one-sided)	0.050														
Standard proportion, p_S	0.150														
Equivalence limit difference, $p_T - p_S, D_0$	0.150														
Test expected proportion, p_T	0.150														
Expected difference, $p_T - p_S, D_1$	0.000														
Power (%)	80														
n per group	71														