Official title: Effect of Phenazopyridine on Prolapse Surgery Voiding Trials

Study number: NCT03065075

Date: February 1, 2017

Study Protocol and Statistical Analysis Plan

Study Protocol

All subjects will receive 200 mg oral phenazopyridine before prolapse surgery, in the hospital's pre-operative area. This is our standard of care in the post-indigo carmine era, for intraoperative ureteral patency verification. This study examines the effect of a second 200 mg dose. [Pharmacokinetic studies show that 90% of a 600 mg/day dose is excreted in the urine over 24 hours. There is minimal risk to receiving one additional dose, since 400 mg over 2 days is well below the recommended dose of 200 mg three times a day.]

For the intervention group, the postoperative day 1 (POD1) 200 mg dose will be ordered to be given at 6am since void trials (VTs) occur later that day, as medically indicated by the subject's recovery.

The primary outcome will be determined by the proportion of subjects who fail a standardized VT prior to discharge. A successful VT is defined as a postvoid residual of less than half of the voided volume.

Statistical Analysis Plan

Comparisons between the intervention and control groups will be performed using Chi square, Fishers exact test (for cell counts <5), Students T-test, and Wilcoxon rank sum test. Intent-to-treat and as-treated analysis of VT results will also be performed. P-values <0.05 will be considered significant. All analyses will be performed using Stata MP 14.2 (StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP).