

# Indigotindisulfonate Sodium as an Aid in Determination of Ureteral Patency in Patient's With Renal Impairment

NCT06085183

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| Status     | RECRUITING      |
| Phase      | Phase 4         |
| Sponsor    | Prove pharm     |
| Enrollment | 48 participants |

## Key Eligibility Criteria

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### Inclusion (11)

- Subjects between e 18 and d 85 years old
- Subjects who signed a written IRB approved, informed consent form
- Subjects scheduled for a surgical procedure in which the patency of the ureter must be assessed by cystoscopy following the procedure.
- An estimated glomerular filtration rate (eGFR) at baseline will be determined using the Modification of Diet in Renal Disease formula (MDRD) and standardized by using individual's body surface area.
- Subject's renal function will be defined based on the following criteria:  
... and 6 more (see full listing online)

### Exclusion (9)

- Subjects with eGFR  $<15$  mL/min or expected need for dialysis in the near future, or having only 1 kidney
- Subjects with known severe hypersensitivity reactions to Bludigo™ or other dyes, including contrast dyes
- Known history of drug or alcohol abuse within 6 months prior to the time of screening visit
- Subjects, as assessed by the Investigator, with conditions/concomitant diseases precluding their safe participation in this study (e.g., major systemic diseases)
- Unable to meet specific protocol requirements (e.g., scheduled visits) or subject is uncooperative or has a condition that could lead to non-compliance with the study procedures  
... and 4 more (see full listing online)

## Locations (1 total)

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Albany Medical Center, Albany, New York, United States