

# Indigotindisulfonate Sodium Injection, USP as an Aid in the Determination of Ureteral Patency

NCT06054880

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Status	RECRUITING
Phase	Phase 4
Sponsor	Prove pharm
Enrollment	116 participants

## Key Eligibility Criteria

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### Inclusion (3)

- 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

### Exclusion (9)

- Subjects with stage 4 or 5 Chronic Kidney Failure as evidenced by a GFR  $\leq$ 30 mL/min (calculated using the MDRD formula and standardized by using individual's body surface area) or 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