Evaluation of Lumitrace for Visualizing Ureters During Abdominopelvic Surgeries

NCT07080008

Status	RECRUITING
Phase	Phase 1
Sponsor	MediBeacon
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (8)

- Age \> 18 years - male or female
- Eligible female non-pregnant subjects who are either not of child-bearing potential or willing to use adequate contraception during the trial
- Males must be willing to practice abstinence or utilize adequate contraception from dosing day to at least 30 days post-dose administration
- For women of child-bearing potential, the subject should have a negative serum pregnancy test on day of surgery, and agrees to one of the following acceptable contraceptive methods used consistently and correctly from the time of consent through 30 days after Lumitrace administration; i.e. abstinence, oral contraceptive either combined or progesterone alone; injectable progesterone, implants of levonorgestrel, estrogenic vaginal ring, percutaneous contraceptive patches, IUD device or system, or male partner sterilization
- Men will not donate sperm during the study and for 30 days following the last dose of Lumitrace

... and 3 more (see full listing online)

Exclusion (10)

- Participant has any serious or uncontrolled physical or psychiatric condition that in the opinion of the investigator would limit the their ability to complete study requirements or may put the subject at increased risk, or compromise the interpretability of study results, which makes the participant unsuitable for study participation
- Participant is anticipated to require ureteral stenting during surgery
- Participant has an active urinary tract infection requiring antibiotic therapy
- Participant has moderate to severe cardiac disease that limits daily functioning (New York Heart Association Class III to IV) or other medical conditions that would impact safety or study compliance
- Participant has any clinically relevant laboratory abnormality that could contraindicate surgery in the opinion of the PI

... and 5 more (see full listing online)

Locations (1 total)

University of Missouri, Kansas, City, School of Medicine; Division of Urogynecology and Reconstructive Pelvic Surgery,, Kansas City, Missouri, United States