A Double Blind, Randomized Controlled Study, Evaluating the Safety and Efficacy of RD2 Ver.02 For the Management of Anal Fistulas

NCT05641844

Status	RECRUITING
Phase	Not Applicable
Sponsor	RedDress Ltd.
Enrollment	110 participants

Key Eligibility Criteria

Inclusion (5)

- Subject is e18 years of age
- Subject has a transsphincteric or long intersphincteric anal fistula (\>1.5 cm), with a seton in place for a minimum of 1 month, deemed eligible for primary or repeat fistula repair by anorectal advancement flap or LIFT: Anterior, posterior or lateral fistula, first or recurrent, at any position circumferentially, with one external opening and one internal opening.
- Subjects is unable or unwilling to receive invasive surgical procedures, anorectal advancement flap or LIFT procedure, and is opting for minimally invasive technique of anal fistula management (i.e., fistula tract debridement and suturing of internal opening).
- Prior to enrollment, during the preceding 3 months from Treatment Visit, subject must undergo a pelvic MRI to evaluate eligibility criteria unable to be assessed clinically.
- Female subjects who are capable of conceiving and all males capable of insemination must use an acceptable form of contraception in order to participate in the study and for 6 months following study procedure (acceptable forms of contraception include condoms for males and contraceptive pills or IUDs for women)

Exclusion (29)

- Subject who has a life expectancy of less than 24 months.
- Subjects who are cognitively impaired and have a healthcare proxy or those who are cognitively impaired and clearly do not understand the contents of the informed consent form.
- Cannot withdraw blood in the required amount (up to 15 mL).
- Women who are pregnant or currently breast feeding.
- Subject is currently receiving (i.e., within the past 30 days) or scheduled to receive systemic steroids (more than 10mg per day).

... and 24 more (see full listing online)

Locations (10 total)

Karen Zaghiyan, M.D, Los Angeles, California, United States
Cleveland Clinic, Weston, Florida, United States
University of Chicago, Chicago, Illinois, United States
... and 7 more locations