Study Evaluating the Safety and Efficacy of an ECM Hydrogel for the Treatment of Anorectal Fistulas

NCT07035925

Status	RECRUITING
Phase	Not Applicable
Sponsor	ECM Therapeutics, Inc.
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (6)

- Male and female subjects at least 18 years of age.
- Provide informed consent
- Non-pregnant females
- Clinical diagnosis of 1 high transsphincteric anorectal fistula, with 1 internal opening and 1-2 external openings, with a single seton in place.
- Seton placement for a minimum of four (4) weeks

... and 1 more (see full listing online)

Exclusion (18)

- Inability to provide informed consent.
- Medical history of Crohn's disease/Ulcerative Colitis.
- Subjects with multiple fistula tracts (defined as \>1 internal opening and/or \>2 external openings), secondary tracts, horseshoe fistulas, J-pouch fistulas, superficial fistulas, ano/recto-vaginal fistulas or rectourethral fistulas.
- Previous fistulotomy/fistulectomy at the target treatment site (a history of these procedures at other locations is not exclusionary).
- Fistula of traumatic origin including obstetric.

... and 13 more (see full listing online)

Locations (2 total)

Dartmouth Hitchcock Medical Center, Lebanon, New Hampshire, United States
University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, United States