

# Mirikizumab in the Treatment of Chronic Inflammatory Conditions of the Pouch

NCT06864403

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Status	RECRUITING
Phase	Phase 4
Sponsor	University of North Carolina, Chapel Hill
Enrollment	25 participants

## Key Eligibility Criteria

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### Inclusion (9)

- Informed consent will be obtained before any study-related procedures
- Age  $\geq$  18 and  $\leq$  80 years
- Diagnosis of Chronic Pouchitis or Crohn's-like disease of the pouch based on the following criteria:
- Chronic Antibiotic-Dependent Pouchitis: Recurrent symptoms of pouchitis (frequency, urgency, bleeding, abdominal pain or cramping, or pelvic discomfort) that respond to antibiotic therapy but relapse shortly after stopping antibiotics, thus necessitating continuous antibiotic therapy to achieve symptom control.
- Chronic Antibiotic Refractory Pouchitis: Lack of response to standard antibiotic therapy, requirement of a longer duration of antibiotic therapy than expected with minimal improvement in symptoms, in association with typical symptoms of pouchitis (frequency, urgency, bleeding, abdominal pain or cramping, or pelvic discomfort).

... and 4 more (see full listing online)

### Exclusion (12)

- Prior exposure to mirikizumab
- Known hypersensitivity to mirikizumab or its metabolites
- Current infection with *Clostridioides difficile*
- Known HIV or active Hepatitis B/C
- Clinically significant liver disease (Primary Sclerosing Cholangitis with LFT's  $<$ 1.5 upper limit of normal can be included)

... and 7 more (see full listing online)

## Locations (5 total)

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UCLA Vatche & Tamar Manoukian Division of Digestive Diseases, Los Angeles, California, United States  
Mayo Clinic, Rochester, Minnesota, United States  
NYU Langone Health, New York, New York, United States

... and 2 more locations