Research Studies at Columbia University Irving Medical Center
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Boomerang Early Feasibility Study
PI: Marco Bertucci Zoccali, MD
Recruitment Status: Recruiting
Intervention/Investigational Device: Neuromodulation/ InterStim™ Neurostimulator for the treatment of **active Crohn's disease and ulcerative colitis**; SNS is a minimally invasive, outpatient procedure performed under conscious sedation. A neurostimulator device with leads stimulates the sacral nerve by delivering electrical impulses to the nerves in the pelvis.

General Inclusion Criteria:

1. Male or female 18 to 75 years of age

2. Disease duration of ≥ 6 months

3. Naive of IBD drugs or stable on IBD drugs regimen

4. Ability and willingness to consent to participate by signing the informed consent form

5. Ability to comply with the protocol and willingness to comply with all follow-up requirements

Ulcerative Colitis-Specific Inclusion Criteria: Patient has active left-sided ulcerative colitis as defined by a Mayo score ≥ 3
Crohn's Disease-Specific Inclusion Criteria: Patient has active Crohn's disease as defined by a CDAI score of > 150 and ≤ 450, and a SES-CD score of > 3.

General Exclusion Criteria

The subject must not meet **ANY** of the following criteria:

1) Any significant medical condition that is likely to interfere with study procedures, device operation, or likely to confound the results of the study

2) History or current evidence of alcohol/drug abuse and psychiatric or personality disorders

3) Any active infections

4) Evidence of bowel perforation or stricture

5) Microscopic, ischemic or infectious colitis

6) Presence of an ileostomy, colostomy, or enteral or parenteral feeding

7) History of cancer (except for localized skin cancers) within 5 years

8) Participation in another clinical trial within 30 days of device implant

9) Investigational drug for the treatment of inflammatory bowel disease within 6 months of device implant

Study Duration: Patients will be followed for 3 years post index procedure.