



STATIC TRIAL: The STopping Aminosalicylate Therapy in Inactive Crohn's Disease A Randomized, Open-label, Non-inferiority Trial (STATIC)

Inclusion Criteria

- Aged 18 years or older in primary or secondary care
- Documented diagnosis of CD previously confirmed by endoscopy and histology at least 3 months prior to enrollment
- Taking any brand or dosage of an oral aminosalicylate for at least 6 months prior to enrollment
- Subject-confirmed compliance with current aminosalicylate therapy (taking at least 75% of prescribed doses)
- CD currently in clinical remission, defined as:
 - A Harvey-Bradshaw Index (HBI) score ≤ 4 at enrollment visit AND
 - No escalation in medication for the treatment of a CD flare within 3 months prior to enrollment AND
 - No use of systemic corticosteroids for CD (2 continuous weeks or more) within the 3 months prior to enrollment AND
- Clinician judgement of disease remission
- Able to participate fully in all aspects of the clinical trial
- Written informed consent obtained and documented



Exclusion Criteria

- A current diagnosis of ulcerative colitis, indeterminate colitis, microscopic colitis, or diverticular disease- associated colitis
- A diagnosis of short-bowel syndrome
- Active perianal disease (note: a history of perianal disease is permitted)
- Active fistulizing disease (note: a history of fistulizing disease is permitted)
- A flare of CD within 3 months prior to enrollment requiring initiation/escalation of medical therapy or surgery
- Use of systemic corticosteroids for CD (2 continuous weeks or more) within 3 months prior to enrollment
- A major resective bowel surgery for CD (ileal resection, ileocecal resection, proctocolectomy, colectomy, enterectomy, ostomy formation and repair, anastomosis/reanastomosis) within 6 months prior to enrollment
- Unwillingness to stop taking aminosalicylates for the duration of the trial
- Untreated bile salt malabsorption that, in the opinion of the investigator, may interfere with accurate study HBI assessment
- Serious underlying disease other than CD that, in the opinion of the investigator, may interfere with the subject's ability to participate fully in the study
- History of active alcohol or drug abuse that, in the opinion of the investigator, may interfere with the subject's ability to comply with the study procedures