

Baricitinib in the Treatment of Intestinal Behçet's Syndrome

NCT06849908

Status	RECRUITING
Phase	Phase 2
Sponsor	Peking Union Medical College Hospital
Enrollment	56 participants

Key Eligibility Criteria

Inclusion (6)

- Refer to the consensus on the diagnosis and treatment of intestinal Behçet's syndrome in China: Patients who meet the 2013 International Criteria for Behçet's Disease (ICBD) and have typical Behçet's syndrome-related intestinal ulcers confirmed by colonoscopy, or patients diagnosed according to the criteria for Behçet's syndrome established by the Korean Behçet's Disease Collaborative Group in 2009;
- Patients have a DAIBD score \leq 40 points or intestinal symptom score \leq 3 points at baseline;
- Endoscopic examination conducted within 60 days before inclusion suggests active intestinal ulcers;
- Patients who have been treated with medium to high-dose steroids (prednisolone equivalent of 0.5-1 mg/kg/day) for more than 1 month continuously, or any immunomodulator/immunosuppressants for more than 3 months regularly or biologics for more than 2 months, as judged by the doctor to be treatment failure or intolerance;
- Currently steroid dose \leq 30 mg prednisolone equivalent, stabilized for \geq 2 weeks, and/or stabilized immunomodulator dose for \geq 4 weeks;

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

Exclusion (15)

- Diagnosis of other diseases such as Crohn's disease, ulcerative colitis, lymphoma, etc.;
- Other active organ damage related to BS requires intensified immunosuppressive therapy, including aneurysms, uveitis, and substantial involvement of the central nervous system; skin lesions and joint involvement can be included;
- Severe organ dysfunction including ALT, AST, TBIL levels exceeding twice the upper limit of normal, creatinine levels exceeding 1.5 times the upper limit of normal, white blood cell count $<$ $3 \times 10^9/L$, ANC $<$ $2 \times 10^9/L$, hemoglobin $<$ 80g/L, platelets $<$ $100 \times 10^9/L$;
- Active infections such as active tuberculosis, active hepatitis B or C, syphilis, chronic Epstein-Barr virus infection, HIV infection, sustained or severe bacterial or viral infections, and history of severe herpes zoster;
- Patients with latent tuberculosis must undergo \geq 3 weeks of prophylactic anti-tuberculosis treatment before inclusion;

... and 10 more (see full listing online)

Locations (2 total)

Peking Union Medical College Hospital, Beijing, Beijing Municipality, China
Peking Union Medical College Hospital, Beijing, China

<https://clinicaltrials.gov/study/NCT06849908>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at ClinicalTrials.gov. Generated by ClinicalTrialsFinder.org.