

A Study of Efficacy and Safety of Hemay005 Tablets in Patients With Behçet's Disease

NCT06145893

Status	RECRUITING
Phase	Phase 3
Sponsor	Ganzhou Hemay Pharmaceutical Co., Ltd
Enrollment	162 participants

Key Eligibility Criteria

Inclusion (9)

- Understanding and voluntarily signing the Informed Consent Form (ICF) for this study;
- Age 18-75 years (inclusive), male or female;
- Diagnosed as BD based on the ICBBD-2013;
- At least 2 oral ulcers present at V1 (screening), and:
 - at least 2 oral ulcers present at V2 (the day of randomization) when V2 occurs 14-56 days after V1; OR
- ... and 4 more (see full listing online)

Exclusion (34)

- Active lesions associated with BD in major organs requiring immunosuppressive treatment, e.g., those in lungs (e.g., pulmonary aneurysm), blood vessels (e.g., thrombophlebitis, recurrent malignant aneurysms), gastrointestinal tract (e.g., gastrointestinal ulcers), and central nervous system (e.g., meningoencephalitis); Note: Patients with refractory BD who experienced gastrointestinal perforation, active bleeding, or obstruction, etc. within 3 months prior to randomization are to be excluded.
- Any clinically significant heart disease (including but not limited to: unstable ischemic heart disease, NYHA III/IV left ventricular failure, or myocardial infarction) or clinically significant 12-lead ECG abnormalities detected during the 6 months prior to screening, which, at the investigator's discretion, may put the subject at safety risk or may interfere with the study assessments;
- Use of the following immunomodulatory therapies:
 - Colchicine within 7 days prior to randomization;
 - Perazathioprine, mycophenolate, baritinib, or tofacitinib within 10 days prior to randomization;
- ... and 29 more (see full listing online)

Locations (22 total)

Beijing Friendship hospital capital medical hospital, Beijing, Beijing Municipality, China
Peking university first hospital, Beijing, Beijing Municipality, China
Peking University People's Hospital, Beijing, Beijing Municipality, China
... and 19 more locations