

A Study of TJ101 Injection Before and After CMC Change Following Subcutaneous Injection in Healthy Adult Male Subjects in China

NCT07300436

Status	RECRUITING
Phase	Phase 1
Sponsor	TJ Biopharma Co., Ltd.
Enrollment	96 participants

Key Eligibility Criteria

Inclusion (4)

- Male subjects aged e 18 and d 45 years;
- Body mass index (BMI): 19-28 kg/m² (inclusive), weight 50-90 kg (inclusive), with BMI calculated as: BMI = weight (kg) / height² (m²);
- Results of physical examination, vital signs, laboratory tests, 12-lead ECG, chest X-ray (posteroanterior view), and abdominal B-scan ultrasound are normal or clinically insignificant if abnormal;
- Fully understand the purpose and requirements of this study, voluntarily participate in the clinical study and sign the written informed consent form (ICF), and are able to complete the entire study process as required.

Exclusion (17)

- (Screening/Admission interview) Known history of allergy to the investigational product, any of its components, or related products; or a history of allergic diseases such as asthma; or allergic diathesis (e.g., known allergy to two or more substances);
 - (Screening/Admission interview) A definite history of diseases of the central nervous, cardiovascular, digestive, respiratory, urinary, or hematological systems, or metabolic disorders, or potential underlying diseases that are judged by the investigator to be clinically significant; or other diseases that the investigator considers unsuitable for participation in a clinical study (e.g., history of mental illness);
 - (Screening/Admission interview) History of severe infection, severe trauma, or major surgery within 6 months prior to screening;
 - (Screening/Admission interview) History of blood donation, blood loss e 400 mL, or blood transfusion (at least one of the above) within 3 months prior to screening; or plan to donate blood within 3 months after the end of the study;
 - Positive test for any of the following infectious diseases: human immunodeficiency virus antibody, hepatitis B surface antigen, hepatitis C virus antibody, Treponema pallidum specific antibody, and syphilis specific antibody;
- ... and 12 more (see full listing online)

Locations (1 total)

Chengdu Xinhua Hospital, Chengdu, Sichuan, China