To Evaluate the Effect of Food on the Pharmacokinetics of Y-4 Tablets in Healthy Subjects

NCT07013773

Status	RECRUITING
Phase	Phase 1
Sponsor	Beijing Tiantan Hospital
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (4)

- Healthy adult male and female subjects, 18-45 years of age (including both ends).
- Body weight e 50 kg for male and e 45 kg for female, body mass index (BMI) within the range of 19 - 28 kg/m2 (including both ends).
- During the screening period, serum creatinine is within the normal range, or the standard creatinine clearance (CLcr) estimated by Cockcroft-Gault formula is e 80 mL/min (for female subject, according to the calculation result × 0.85 .
- Subjects who are able to understand and give their signed informed consent before any trial related procedures are performed.

Exclusion (24)

- Subjects who are known to be allergic to pregabalin, riluzole or any excipients of Y-4 tablets (microcrystalline cellulose, Copovidone, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate and Opadry amb a), have allergic diseases or allergic constitution;
- Subjects who have special requirements for diet and cannot follow the unified diet;
- Physical examinations, vital signs, 12-lead electrocardiograms (ECG), chest X-ray (front position), laboratory tests (hematology, serum chemistry, coagulation test, urinalysis, etc.) and other screening tests found abnormalities that the researchers judged to be of clinical significance;
- Subjects who have experienced angioedema in the past (such as swelling of the face, mouth (tongue, lips, and gums), and neck (pharynx and throat));
- History of dizziness or vertigo with clinical significance, or disease of inner ear known to cause dizziness or vertigo;

... and 19 more (see full listing online)

Locations (1 total)

Beijing Tiantan Hospital, Capital Medical University Beijing, Beijing, Beijing Municipality, China