Bioequivalence Study of BGM0504 Injection

NCT07382908

Status	RECRUITING
Phase	Phase 1
Sponsor	BrightGene Bio-Medical Technology Co., Ltd.
Enrollment	144 participants

Key Eligibility Criteria

Inclusion (4)

- Age 18-55 years (inclusive).
- Male weight e50 kg, female weight e45 kg, and overweight (24.0 d BMI \< 28.0 kg/m²) or obese (BMI e 28.0 kg/m²).
- From signing the ICF until 3 months after dosing, no pregnancy plan and willing to use effective contraception to avoid pregnancy or causing partner pregnancy, and no plan for sperm/egg donation.
- The participant fully understands the trial purpose, nature, methods, and potential adverse reactions, can complete the trial according to the protocol, has good living habits, can maintain good communication with the investigator, and voluntarily signs the ICF.

Exclusion (10)

- History of severe allergies or severe specific allergic diseases/history (asthma, urticaria, eczematous dermatitis, etc.) or allergic constitution (allergic to two or more foods or drugs), known or suspected allergy to any excipient of BGM0504 Injection.
- Previous diagnosis of type 1 or type 2 diabetes, or clinically significant abnormal HbA1c at screening.
- Family history of medullary thyroid carcinoma or multiple endocrine neoplasia type 2 syndrome.
- History of acute/chronic pancreatitis, pancreatic injury, or other high-risk factors for pancreatitis.
- Past or screening findings of digestive system diseases that may increase participant risk.

... and 5 more (see full listing online)

Locations (1 total)

Hangzhou First People's Hospital, Hangzhou, Zhejiang, China