Evaluate the Pharmacokinetics, Pharmacodynamics, Safety and Tolerability of BGM1812 Injection Following Single and Multiple Subcutaneous Administration in Normal to Overweight or Obese But Otherwise Healthy Men and Women

NCT07224399

Status	RECRUITING
Phase	Phase 1
Sponsor	BrightGene Bio-Medical Technology Co., Ltd.
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (6)

- Capable of understanding the written informed consent document; willingly provides valid, signed written informed consent; willing and able to comply with the schedule, requirements and restrictions of the study.
- Body mass index (BMI) meeting one of the following requirements:
- Between e 30.0 kg/m2 and d 40.0 kg/m2 (obese) (for Cohort 3-6); OR
- Between e 27.0 kg/m2 and \< 30.0 kg/m2 (overweight) with at least 1 of the following: One or more symptoms of prediabetes (impaired fasting plasma glucose and/or abnormal glucose tolerance), grade 1 hypertension, simple fatty liver or dyslipidemia (For Cohort 3- 6); OR
- Between e 23.0 kg/m2 and \< 27.0 kg/m2 healthy subjects (for Cohort 1 and Cohort 2)

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

Exclusion (5)

- Have allergic predisposition (allergic to 3 or more foods or drugs), or are allergic to amylin agonist-based therapeutic agents or suffer from severe allergic diseases (asthma, urticaria, eczematous dermatitis).
- Known type I/II diabetes.
- Has underwent gastric bariatric surgery in the past, or has had liposuction or fat removal within 1 year before screening, or plan to have bariatric surgery, liposuction or abdominal fat removal during the study period or other surgery that would obviously affect the body weight.
- History of acute or chronic pancreatitis or pancreatic injury.
- Has any other conditions or disorders deemed unsuitable for including in the study, in the opinion of the Investigator.

Locations (1 total)

Pharmaron CPC, Inc, Baltimore, Maryland, United States