

A Mass Balance Study of [14C] MT1013 in Hemodialysis Subjects With Secondary Hyperparathyroidism

NCT07284043

Status	RECRUITING
Phase	Phase 1
Sponsor	Shaanxi Micot Pharmaceutical Technology Co., Ltd.
Enrollment	6 participants

Key Eligibility Criteria

Inclusion (5)

- Male or postmenopausal female participants, aged 18 years or older, with a confirmed diagnosis of SHPT.
- The BMI is between 18 kg/m² and 35 kg/m²;
- The subjects must undergo regular maintenance hemodialysis three times a week for at least three months
- Within 14 days prior to randomization, subjects must have serum calcium level ≤ 8.4 mg/dL;
- Subject capable of understanding written information, willing to participate in, and provide a written informed consent;

Exclusion (9)

- The subjects underwent parathyroidectomy within 6 months prior to screening, or plan to undergo parathyroidectomy or ablation or radiation during the study;
- Gastrointestinal bleeding or peptic ulcer medical history within 6 months prior to screening;
- The subjects had myocardial infarction or had undergone coronary angioplasty or coronary artery bypass grafting within 6 months before screening.
- Subjects with severe uncontrolled hypertension, defined as systolic blood pressure > 180 mmHg and/or diastolic blood pressure > 110 mmHg;
- History of epileptic seizures or ongoing epilepsy related treatment within 1 year prior to screening;

... and 4 more (see full listing online)

Locations (1 total)

The First Affiliated Hospital of Shandong First Medical University (Shandong Qianfoshan Hospital), Jinan, Shandong, China