To Evaluate the Safety, Tolerability, Pharmacokinetics and Food Effects of IMM-H014 in Healthy Subjects

NCT06216041

Status	RECRUITING
Phase	Phase 1
Sponsor	Changchun Intellicrown Pharmaceutical Co. LTD
Enrollment	138 participants

Key Eligibility Criteria

Inclusion (4)

- Subjects can voluntarily participate in the clinical trial, sign informed consent before the trial, fully understand the trial content, process and possible adverse events, and complete the study in accordance with the requirements of the trial protocol;
- Subjects can use effective contraceptive methods, such as abstinence, condoms, IUD use, and dual barrier method (such as condom plus diaphragm), within 6 months from the beginning of screening to the last trial drug administration;
- years of age, male and female (including 18 and 45 years);
- Male weight e50kg, female weight e45kg; Body mass index (BMI) in the range of 18-28 kg/m2 (including the cut-off value); 5 Vital signs and physical examination with normal or abnormal has no clinical significance.

Exclusion (22)

- Clinical history of drug allergy or specific allergic diseases (asthma, urticaria), or known or suspected allergic history to experimental drugs and related excipients;
- Subjects who have used any prescription drugs, over-the-counter drugs, Chinese herbal medicines and health products within 2 weeks before screening;
- Clinical laboratory examination (blood routine, urine routine, blood biochemistry, coagulation function, virology examination, thyroid function), abdominal color Doppler ultrasound (liver, gallbladder, spleen, pancreas, kidneys, adrenal gland), chest radiography and other abnormalities with clinical significance; Or other clinically significant diseases (including but not limited to gastrointestinal tract, kidney, liver, nerve, blood, endocrine, tumor, lung, immune, mental or cardiovascular and cerebrovascular diseases) within 6 months before screening;
- Subjects who ate diets (including grapefruit or grapefruit products, pitaya, mango, etc.) that may affect drug metabolism within 7 days before screening, or had strenuous exercise, or the researchers thought that there were other dieters that affected drug metabolism, absorption, distribution, metabolism and excretion;
- A family history of a first-degree relative (i.e., biological parent, sibling, or child) with a risk factor for tip torsional ventricular tachycardia, or a family history of short QT syndrome, long QT syndrome, sudden unexplained death in youth (less than/etc. 40 years old), or sudden infant death syndrome;

... and 17 more (see full listing online)

Locations (1 total)

The first Bethune hospital of Jilin University, Changchun, Jilin, China