A Trial to Evaluate the Efficacy and Safety of SHR-1918 in Patients With Hyperlipidemia

NCT07230730

Status	RECRUITING
Phase	Phase 3
Sponsor	Beijing Suncadia Pharmaceuticals Co., Ltd
Enrollment	900 participants

Key Eligibility Criteria

Inclusion (4)

- the age must be at least 18 years old, and both men and women are eligible;
- the patient was receiving a stable dose of statins at the time of screening,, and the fasting LDL-C met: For individuals with extremely high risk of ASCVD, LDL-Ce1.4 mmol/L; for those with very high risk of ASCVD, LDL-Ce1.8 mmol/L; and for those with medium and high risk of ASCVD, e2.6 mol/L;
- Fasting TGe2.3 and d5.6 mmol/L;
- Understand the research procedures and methods, voluntarily participate in this trial and sign the informed consent form in person

Exclusion (5)

- poorly controlled hypertension (systolic blood pressure e160 mmHg and/or diastolic blood pressure e100 mmHg) at the time of screening or before randomization
- Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) or ^{3} glutamyl transferase (GGT) \> 3× upper limit of normal (ULN), or total bilirubin \> 2×ULN
- Thyroid stimulating hormone (TSH) is lower than the lower limit of normal (LLN) or greater than 1.5×ULN
- The estimated glomerular filtration rate (eGFR) is less than 30 mL/min/1.73m2
- Previously suffering from diseases that have a significant impact on blood lipid levels, such as nephrotic syndrome, severe liver diseases, Cushing's syndrome, etc

Locations (1 total)

The Second Affiliated Hospital Zhejiang University School of Medicine, Hangzhou, Zhejiang, China