

Clinical Exploration Trial of YOLT-101 in the Treatment of Familial Hypercholesterolemia (FH)

NCT06458010

Status	RECRUITING
Phase	Early Phase 1
Sponsor	RenJi Hospital
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (9)

- Male or female, aged 18 to 75 years inclusive, at the time of signing informed consent.
- Meets the diagnostic criteria for familial hypercholesterolemia.
- At screening, there is a mutation in the PCSK9 and/or ApoB and/or LDLR gene.
- At screening, weight is ≤ 40 kg, and Body Mass Index (BMI) is ≤ 18 kg/m².
- At screening, subjects must meet the following laboratory criteria:

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

Exclusion (25)

- Within at least 14 days (or 5 half-lives of the drug, whichever is longer, for small molecule/small nucleic acid drugs) or 2 months (for biological agents such as PCSK9 inhibitors) or 1 year (for PCSK9 small nucleic acid drugs) before accepting the study medication, those who have used prescription drugs that affect lipid metabolism other than statins, or those who have used any non-prescription drugs affecting lipid metabolism within at least 14 days before accepting the study medication (such as traditional Chinese medicine/patent Chinese medicine, vitamins, fish oil (> 1000 mg/day), drugs or health products containing red yeast rice, etc.; except for those who have been on stable non-cyclic hormone replacement therapy for more than 8 weeks and agree not to change the treatment plan for at least 28 days after receiving the trial medication); those who are currently participating in other clinical studies of lipid-lowering drugs and have used study medication.
- Patients with poorly controlled hypertension (systolic blood pressure (SBP) ≥ 160 mmHg and/or diastolic blood pressure (DBP) ≥ 100 mmHg).
- Patients with poorly controlled diabetes (glycated hemoglobin $> 8.5\%$).
- Those allergic to drugs or components of LNP-mRNA vaccines contained in lipid nanoparticles (LNP), or those who have experienced adverse reactions due to LNP-based drug treatment, such as: 4.1 After receiving LNP-based drug treatment, ALT or AST $> 3.0 \times$ ULN; 4.2 After receiving LNP-based drug treatment, INR > 1.5 or APTT/d-dimer $> 1.5 \times$ ULN; 4.3 Any infusion reaction that requires clinical intervention or slows down or stops the infusion of LNP-based drug treatment; 4.4 Any other adverse reactions deemed related to LNP-based drug treatment by the investigator.
- Within 3 months before screening, those who smoke more than 5 cigarettes per day or consume an equivalent amount of nicotine or nicotine replacement products.

... and 20 more (see full listing online)

Locations (1 total)

Department of Liver Surgery, Ren Ji Hospital, School of Medicine, Shanghai Jiao Tong University, Shanghai, Shanghai Municipality, China

<https://clinicaltrials.gov/study/NCT06458010>

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