

# NGGT006 Gene Therapy for Homozygous Familial Hypercholesterolemia

NCT06125847

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Status	RECRUITING
Phase	Early Phase 1
Sponsor	First Affiliated Hospital Xi'an Jiaotong University
Enrollment	12 participants

## Key Eligibility Criteria

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### Inclusion (12)

- Voluntarily sign informed consent form;
  - Male or female, 12 d age d 55 years (first patiente 18 years), diagnosed as homozygous familial hypercholesterolemia with genetic confirmation of two mutant alleles of the LDL receptor (LDLR) gene;
  - AAV8 neutralizing antibodies can be negative or reduced to negative levels through methods such as plasma exchange.
  - Untreated LDL-C e10 mmol/L (386mg/ dL) or treated LDL-C e7 mmol/L (270mg/ dL) together with cutaneous or tendon xanthoma before age 18 years;
  - Had been on stable medication for e30 days if receiving lipid-lowering therapy (or e60 days if receiving alirocumab or evolocumab) prior to screening and not scheduled for addition of new drugs or dose adjustments during the study;
- ... and 7 more (see full listing online)

### Exclusion (19)

- Positive for hepatitis B surface antigen, hepatitis C, human immunodeficiency virus (HIV) or syphilis test;
  - Clinically significant abnormalities in liver function test: alanine aminotransferase (ALT) e2 x upper limit of normal (ULN) and/or aspartate aminotransferase (AST) e2 x ULN;
  - Baseline blood pressure e160/100 mmHg (1 repeat measurement is allowed);
  - Uncontrolled myocardial infarction or heart failure, or had surgery plan within 1 year;
  - Diabetes diagnosed within 3 months or with poor control (HbA1c e9%);
- ... and 14 more (see full listing online)

## Locations (1 total)

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First Affiliated Hospital of Xian Jiaotong University, Xi'an, Shaanxi, China

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<https://clinicaltrials.gov/study/NCT06125847>

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