

# Gene Therapy Clinical Trial for the Treatment Of Leber's Hereditary Optic Neuropathy

NCT04912843

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 2, Phase 3
<b>Sponsor</b>	Wuhan Neurophth Biotechnology Limited Company
<b>Enrollment</b>	102 participants

## Key Eligibility Criteria

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### Inclusion (16)

- Age at signing of informed consent form
- In Part 1, the age of the subjects must be e 18 years old and d 75 years old
- In Part 2, the age of the subjects must be e 12 years old and d 75 years old, and the 6 evaluable subjects must be monitored for at least 6 weeks during the safety run-in phase. If SRC believes that there is no safety issue, the randomized double-blind control study will be initiated
- Subject Type and Disease Characteristics
- The clinical manifestation caused by LHON is vision loss, with a visual acuity of e 0.5 LogMAR in BCVA in either eye
- The genotype test result is that there is G11778A mutation in ND4 gene, and there are no other primary LHON-associated mutations in the mitochondrial DNA (mtDNA) (ND1[G3460A] or ND6[T14484C]) (confirmed by a CLIA-certified international laboratory)

... and 11 more (see full listing online)

### Exclusion (23)

- Subjects who meet any of the following criteria will be excluded from the study:
- Any known allergy and/or hypersensitivity to the study drug or its constituents
- Contraindication to IVT injection in any eye
- IVT drug delivery to any eye within 30 days prior to the screening visit
- History of vitrectomy in either eye

... and 18 more (see full listing online)

## Locations (1 total)

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Beijing Tongren Hospital, Capital Medical University, Beijing, China