

A Study of EH002 Gene Therapy for Otoferlin Gene Mutation-mediated Hearing Loss

NCT06722170

Status	RECRUITING
Phase	Not Applicable
Sponsor	Yilai Shu
Enrollment	24 participants

Key Eligibility Criteria

Inclusion (6)

- The participant and/or their legal guardian must provide informed consent before the study, voluntarily sign the written informed consent form, and be willing to attend follow-up visits as scheduled by the study.
- The participant must communicate effectively with the investigator and comply with the investigator's requirements, with the assistance of a legal guardian if necessary. Young children without mature language skills must be able to cooperate and comply with the investigator's requirements with the help of a legal guardian.
- The participant and/or legal guardian must understand the study correctly and have appropriate expectations regarding the potential benefits.
- The participant must be at least 6 months old, with no restrictions on gender.
- The participant must be diagnosed with DFNB9 congenital deafness, confirmed by genetic testing showing homozygous or compound heterozygous mutations in the OTOF gene.

... and 1 more (see full listing online)

Exclusion (15)

- The genetic diagnosis does not indicate an OTOF mutation.
- Other types of deafness that are unsuitable for otological surgery, such as middle- or inner-ear developmental abnormalities or malformations, vestibulocochlear nerve abnormalities, conductive hearing loss, mixed hearing loss, or malformation syndromes, as detected by CT or MRI scans within 3 months.
- Pre-existing otological conditions that would interfere with the planned surgery or the interpretation of study endpoints, such as acute or chronic otitis media, Meniere's disease, acoustic neuroma, or unrecovered sudden sensorineural hearing loss.
- A history of substance abuse, or treatment with any known ototoxic drugs (e.g., aminoglycosides, cisplatin, loop diuretics) within the last 6 months, or antiviral medications or immunotherapy within the last 3 months, or vaccination within the last month.
- Individuals with compromised immunity or a history of immunodeficiency, including HIV-positive status, other acquired or congenital immunodeficiency disorders, or a history of organ transplantation.

... and 10 more (see full listing online)

Locations (2 total)

The First Affiliated Hospital of Zhengzhou University, Zhengzhou, Henan, China
Eye & ENT Hospital of Fudan University, Shanghai, Shanghai Municipality, China

<https://clinicaltrials.gov/study/NCT06722170>

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