

Perceptual Evaluation and Rehabilitation System Development for Congenital Hearing Loss

NCT07024524

Status	RECRUITING
Phase	Not Applicable
Sponsor	Eye & ENT Hospital of Fudan University
Enrollment	210 participants

Key Eligibility Criteria

Inclusion (5)

- For Congenital Deafness Group: Patients with congenital hearing loss with hearing thresholds ≥ 65 dB who have received hearing aids, cochlear implantation, or gene therapy; Age between 1 and 35 years old, regardless of gender.
- For Healthy Controls Group: Participants with normal hearing thresholds (≤ 20 dB) whose age and gender matched to the patient group.
- Mandarin Chinese as the native language. Participants and/or their guardians must provide informed consent before the trial, voluntarily sign a written consent form, and commit to receive evaluation at specified time points.
- Capable of effective communication with researchers under the guardian's assistance and willing to cooperate and comply with the researchers' requirements.
- Participants and/or their guardians should have a correct understanding of the trial and appropriate expectations regarding potential benefits.

Exclusion (5)

- Presence of other otological disorders that may interfere with the surgical outcome or interpretation of study endpoints, such as otitis media, Meniere's disease, etc.
- Presence of other severe congenital diseases, such as congenital heart disease. Presence of severe systemic diseases or in the acute onset of diseases, such as pulmonary tuberculosis, active hepatitis B or C infection, active herpes zoster infection, pancreatitis, renal insufficiency, etc.
- Individuals with low immunity, a history of immune deficiency or organ transplantation.
- Individuals with a history of neurological, mental disorders, or moderate-to-severe cognitive dysfunction, such as epilepsy, dementia, autism spectrum disorders, etc.
- Any other conditions for which the investigators consider the subject unsuitable for participation in this clinical study.

Locations (1 total)

Eye & ENT Hospital of Fudan University, Shanghai, China

<https://clinicaltrials.gov/study/NCT07024524>

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