

Single-Sided Deafness and Asymmetric Hearing Loss

NCT04506853

Status	RECRUITING
Phase	Not Applicable
Sponsor	Med-EI Corporation
Enrollment	65 participants

Key Eligibility Criteria

Inclusion (7)

- Five years of age or older at the time of implantation
- Unilateral profound hearing loss, as defined by a pure-tone average (500, 1000, 2000, and 4000 Hz) of 90 dB or greater in the ear to be implanted
- Sensorineural hearing loss in the ear to be implanted, as defined by an air-bone gap less than or equal to 10 dB at two or more frequencies out of 500, 1000, 2000, and 4000 Hz and a diagnosed pathology of the outer or middle ear
- Normal hearing or mild to moderate hearing loss in the non-implanted ear, as defined by a pure-tone average (500, 1000, 2000, and 4000 Hz) of 55 dB or less
- Word recognition in the ear to be implanted of 5% or less on CNC word score in quiet
- ... and 2 more (see full listing online)

Exclusion (7)

- Duration of profound hearing loss of 10 years or more
- Absence of cochlear development or non-functionality of cochlear nerve
- Other retrocochlear hearing loss
- Evidence of severe cochlear malformation (i.e., common cavity or ossification)
- External or middle ear infection
- ... and 2 more (see full listing online)

Locations (6 total)

Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, Illinois, United States
University of Iowa, Iowa City, Iowa, United States
New York Eye and Ear Infirmary, New York, New York, United States
... and 3 more locations

<https://clinicaltrials.gov/study/NCT04506853>

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