

Investigation to Evaluate the Safety and Effectiveness of Cochlear Implantation in Children and Adults With Unilateral Hearing Loss/Single-sided Deafness

NCT05318417

Status	RECRUITING
Phase	Not Applicable
Sponsor	Cochlear
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (13)

- Individuals 18 years or older (Group A)
 - Ear to be Implanted:
 - Severe sensorineural hearing loss (HL) defined as: Pure-tone average at 0.5, 1, 2, 4 kHz ≥ 80 dB HL ; Aided Consonant-Nucleus-Consonant Test (CNC) score $\leq 5\%$ and
 - Normal Hearing Ear:
 - Normal or near normal hearing defined as an average of (0.5, 1, 2, 4kHz) ≤ 30 dB HL
- ... and 8 more (see full listing online)

Exclusion (13)

- Ossification, abnormal cochlear nerve or any other cochlear anomaly that might prevent complete insertion of the electrode array
 - Previous cochlear implantation
 - Hearing loss of neural or central origin, including auditory neuropathy
 - Duration of profound sensorineural HL ≥ 10 years per self-report
 - Active / chronic middle-ear infection; conductive HL in either ear
- ... and 8 more (see full listing online)

Locations (8 total)

Stanford University, Palo Alto, California, United States
Rocky Mountain Ear Center, Englewood, Colorado, United States
University of Iowa, Iowa City, Iowa, United States
... and 5 more locations