

A Pivotal Study to Evaluate the Clinical Benefit, Performance and Safety of a Totally Implantable Cochlear Implant (TICI) System in Adults

NCT07287124

Status	RECRUITING
Phase	Not Applicable
Sponsor	Cochlear
Enrollment	56 participants

Key Eligibility Criteria

Inclusion (7)

- Individuals aged 18 years and older at time of consent.
 - Clinically established sensorineural hearing loss (SNHL) defined by a four frequency (500, 1000, 2000, 4000 Hz) pure-tone average unaided threshold (PTA4) of e70 dB HL in the ear to be implanted.
 - Compromised functional hearing in the aided condition defined as d40% correct on a word recognition test in the ear to be implanted.
 - Clinically established SNHL defined by a four-frequency (500, 1000, 2000 & 4000 Hz) pure-tone average unaided threshold (PTA4) of e30 dB HL in the contralateral ear.
 - Candidate is a fluent speaker in the language used to assess speech perception performance as determined by the investigator.
- ... and 2 more (see full listing online)

Exclusion (19)

- Prior cochlear implantation, in either ear, or medical plan for cochlear implantation during the clinical investigation, contralateral to the ear to be implanted.
 - Candidates with single-sided deafness as determined by the investigator.
 - Intra-axial (within-the-brain) lesions or deafness due to lesions of the acoustic nerve affecting the ear to be implanted.
 - Middle ear infection (including acute otitis media, chronic otitis media, suppurative otitis media, or serous drainage) in the ear to be implanted either at the time of surgery or within 3 months prior to enrolment.
 - Presence of a tympanic membrane perforation or a history of otologic surgery within 3 months prior to enrolment, in the ear to be implanted.
- ... and 14 more (see full listing online)

Locations (11 total)

Rocky Mountain Ear Center, Englewood, Colorado, United States
University of Miami School of Medicine, Miami, Florida, United States
University of Iowa, Iowa City, Iowa, United States
... and 8 more locations

<https://clinicaltrials.gov/study/NCT07287124>

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