

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

NCT07139327

Status	RECRUITING
Phase	Not Applicable
Sponsor	Cochlear
Enrollment	36 participants

Key Eligibility Criteria

Inclusion (8)

- Individuals aged 18 years and older at time of consent.
- Clinically established post-linguistic moderately severe to profound sensorineural hearing loss (PTA4 of ≥ 55 dB HL), in the ear to be implanted.
- Meets local candidacy criteria for cochlear implantation.
- Compromised functional hearing with a hearing aid in the ear to be implanted, as determined by the investigator.
- Willing to undergo unilateral cochlear implantation.

... and 3 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 (8 total)

Royal Prince Alfred Hospital, Camperdown, New South Wales, Australia
Macquarie University Hospital, Macquarie, New South Wales, Australia
Westmead Private Hospital, Westmead, New South Wales, Australia

... and 5 more locations