Safety and Effectiveness of Cochlear Implantation in an Expanded Adult Population

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Individuals 18 or older at the time of consent * Meets the following audiometric criteria for the ear to be implanted: clinically established sensorineural hearing loss (SNHL) defined by a four frequency pure tone average (PTA) at 500, 1000, 2000, \& 4000 Hz of: ≥60 dB HL and compromised functional hearing in the aided condition defined as \<50% correct on a word recognition test * Meets the following audiometric criteria for the non-implanted contralateral ear: clinically established SNHL defined by a four frequency PTA at 500, 1000, 2000, \& 4000 Hz of \>30 dB HL * Candidate is a fluent speaker in the language used to assess speech perception performance as determined by the investigator. * Willing and able to provide written informed consent.

Exclusion Criteria:

* Meets current indications on audiometric thresholds for traditional adult CI candidates (i.e., bilateral moderate to profound hearing loss in the low frequencies and profound \[≥ 90 dB HL\] hearing loss in the mid to high speech frequencies) * Absence of cochlea development or a cochlear nerve * Presence of active middle ear infection in the ear to be implanted * Tympanic membrane perforation in the presence of active middle ear disease in the ear to be implanted * Medical or psychological conditions that contraindicate general anaesthesia, surgery, or participation in the clinical investigation. * Existing contralateral cochlear implant or medical plan to implant a contralateral cochlear implant during the clinical investigation. * Pregnant or breastfeeding women. Women who plan to become pregnant during the course of the clinical investigation. * Unrealistic expectations on the part of the participant, regarding the possible benefits, risks, and limitations that are inherent to the surgical procedure(s) and prosthetic devices as determined by the investigator. * Additional disabilities that may affect the participant's participation of safety during the clinical investigation. * Unable or unwilling to comply with all of the requirements of the clinical investigation as determined by the investigator. * Investigator site personnel directly affiliated with this study and/or their immediate families; immediate family is defined as a spouse, parent, child, or sibling. * Employees of Cochlear. * Current participation, or participation in another interventional clinical study/trial in the past 30 days, involving an investigational drug or device (unless the other investigation was/is a Cochlear sponsored investigation and determined by the investigator or Sponsor to not impact this investigation.

Conditions & Interventions

Interventions:
DEVICE: Cochlear™ Nucleus® System
Conditions:
Hearing Loss, Sensorineural, Hearing Loss, Bilateral
Keywords:
Cochlear implant, Sensorineural hearing loss, Safety, Efficacy

More Information

Contact(s): Lavin Entwisle - lentwisle@cochlear.com
Principal Investigator:
Phase: NA
IRB
Number:
System ID: NCT06293482
