Evaluating How a Tinnitus Implant Affects Tinnitus Loudness in Adults With Chronic Tinnitus and Varying Levels of Hearing Loss

NCT06641999

Status	RECRUITING
Phase	Not Applicable
Sponsor	Cochlear
Enrollment	16 participants

Key Eligibility Criteria

Inclusion (10)

- years or older.
- Normal hearing to moderately severe sensorineural hearing loss defined as a pure tone average (PTA) at 500, 1000, 2000 and 4000 Hz less than 65 dB HL in both ears (separately) and best-aided phoneme recognition score more than or equal to 80% in both ears (separately).
- Unilateral or asymmetric subjective (no pulsatile) tinnitus. In case of asymmetric tinnitus, the worst ear must be implanted.
- Tinnitus duration of at least 6 months.
- Severe tinnitus loudness determined by a. VAS-L score in the severe range i.e. 50-100/100 b. TFI score in the severe range i.e. 52-90/100

... and 5 more (see full listing online)

Exclusion (11)

- Pulsatile tinnitus.
- Any anatomical or structural abnormalities of the inner ear, cochlear nerve, or brainstem that would negatively impact response to study intervention (determined in a temporal bone CT and if necessary (e.g. possibility of vestibular/acoustic schwannoma) by a MRI scan of the head (of sufficient quality at the discretion of the investigator) not more than five years old at the time of enrolment
- Medical contraindications limiting correct placement, activation, or treatment (determined by medical history; contraindications include brain or major ear surgery, brain or temporal bone tumor(s), recurrent ear infections within the last year, otosclerosis, prior major head trauma that results in sudden injury that causes damage to the brain and results in lasting cognitive impairment).
- Any medical condition, including mental illness or substance abuse, deemed by the Investigator to likely interfere with a patient's ability to sign informed consent, cooperate and/or participate in the study, or interfere with the interpretation of the results (incl. pregnant or breastfeeding women or patients with unrealistic expectations).
- Presence of clinically diagnosed depression or anxiety determined by a psychological state evaluation (if PHQ-9 \> 9 or GAD-7 \> 9).

... and 6 more (see full listing online)

Locations (2 total)

Antwerp University Hospital (UZA), Edegem, Belgium, Belgium
University Medical Center Utrecht, Utrecht, Netherlands