# Vestibular Implantation to Treat Adult-Onset Bilateral Vestibular Hypofunction

NCT05674786

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| **Status** | RECRUITING |
| **Phase** | Not Applicable |
| **Sponsor** | Johns Hopkins University |
| **Enrollment** | 8 participants |

## Key Eligibility Criteria

### Inclusion (11)

- Adults age 22-90 years diagnosed with ototoxic, idiopathic or non-ototoxic/non-central bilateral vestibular hypofunction inadequately responsive to vestibular rehabilitation for greater than 1 year as determined by pre-inclusion history, vestibular testing and clinical examination conducted by a board-certified neurotologist, neurologist or other physician skilled in diagnosis of vestibular disorders
- Hearing status: (1) Hearing in the candidate ear for implantation is equivalent to or worse than that in the contralateral ear; and (2) hearing in the contralateral ear is good enough to allow functional communication in case hearing in the implanted ear is lost after implantation. Specifically, the contralateral ear must satisfy all of the following criteria:
- /1/2/4 kHz pure-tone-average threshold (PTA) hearing better than (i.e., less than) 70 dB HL; and
- ear-specific sentence recognition score using the recorded AzBio Sentence Test presented at 60 dB SPL-A in quiet must be \>60% when tested under either the unaided condition or, if 0.5/1/2/4 kHz PTA\>50 dB, the best-aided condition; and
- ear-specific word recognition score using the recorded Consonant-Nucleus-Consonant (CNC) Word Recognition Test presented at 60 dBHL in quiet must be \>60% when tested under either the unaided condition or, if 0.5/1/2/4 kHz PTA\>50 dB, the best-aided condition

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

### Exclusion (23)

- Inability to understand the procedures and the potential risks involved as determined by study staff
- Inability to participate in study procedures due to blindness, d ±10° neck range of motion, cervical spine instability, ear canal stenosis or malformation sufficient to prevent caloric testing
- Diagnosis of acoustic neuroma/vestibular schwannoma, chronic middle ear disease, cholesteatoma, or central nervous system causes of vestibulo-ocular reflex dysfunction, including chronic and continuing use of medications, drugs or alcohol at doses sufficiently great to interfere with vestibular compensation
- Vestibular dysfunction known to be caused by reasons other than labyrinthine injury due to ototoxicity, ischemia, trauma, infection, Meniere's disease, or genetic defects known to act on hair cells
- Lack of labyrinth patency or vestibular nerve as determined by MRI of the brain with attention to the internal acoustic meatus

... and 18 more (see full listing online)

## Locations (1 total)

Johns Hopkins School of Medicine, Baltimore, Maryland, United States