

# A Study to Evaluate the Safety and Performance of a Vestibular Implant in Adults to Provide Balance Restoration

NCT06805175

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Cochlear
Enrollment	18 participants

## Key Eligibility Criteria

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### Inclusion (10)

- Adults of 18 years or older with bilateral vestibulopathy >1 year of evolution without benefit from conventional rehabilitation treatment. Symptoms unlikely to improve according to clinicians' estimation.
- Hearing impairment ranging from:
  - Early feasibility stage (first 6 subjects enrolled): moderate to severe hearing loss with PTA of 41-70 dB HL on the ear to be implanted.
  - Late feasibility stage (12 subjects): normal hearing to severe hearing loss with PTA > 70 dB HL on the ear to be implanted.
- Patients diagnosed with bilateral vestibulopathy or probable bilateral vestibulopathy based on the consensus document of the Barany Society on vestibular implant candidate criteria for research [van de Berg et al., 2020]:  
... and 5 more (see full listing online)

### Exclusion (23)

- Dynamic Gait Index < 18 and Functional Gait Assessment < 22
- Ossification or other inner ear anomalies that prevent full insertion of electrodes.
- Middle ear disorders including conductive hearing loss.
- Retro cochlear or central origins of hearing impairment.
- Medical contraindications for surgery.  
... and 18 more (see full listing online)

## Locations (3 total)

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ZAS Augustinus, Antwerp, Wilrijk, Belgium

C.H.U. Insular & Materno-Infantil Hospital.(SCS) Las Palmas University. (ULPGC), Las Palmas de Gran Canaria, Las Palmas de Gran Canaria, Spain

Clinica Universidad de Navarra (CUN), Pamplona, Navarre, Spain

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<https://clinicaltrials.gov/study/NCT06805175>

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