Otoferlin Gene-mediated Hearing Loss Natural History Study

NCT05572073

Status RECRUITING
Sponsor Akouos, Inc.
Enrollment 150 participants

Key Eligibility Criteria

Inclusion (5)

- Clinical presentation of bilateral sensorineural hearing loss (SNHL), including auditory neuropathy (AN) / auditory neuropathy spectrum disorder (ANSD) phenotype or medical history of AN / ANSD phenotype earlier in life
- Mutation(s) in the otoferlin gene
- Able and willing to comply with all study requirements, as evidenced by successful completion of the informed consent (and assent, if applicable) process
- Additional Criteria for Inclusion in the Prospective Phase:
- Presence of OAE / CM and absent / abnormal ABRs in at least one ear (that does not have a cochlear implant) within 12 months prior to or at the Month 0 visit

Exclusion (7)

- Unwillingness or inability of the potential participant and/or legally authorized representative to comply with all protocol requirements
- Presence of cochlear nerve deficiency and/or cochlear nerve dysplasia
- Additional Criteria for Exclusion from the Prospective Phase:
- Presence of bilateral cochlear implants at the time of record review or planned within the next 6 months
- Presence of middle ear or auditory brainstem implant(s) at the time of record review or planned within the next 6 months

... and 2 more (see full listing online)

Locations (10 total)

University of Iowa, Iowa City, Iowa, United States
Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, United States
Children's Hospital of Philadelphia, Philadelphia, Pennsylvania, United States
... and 7 more locations

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at ClinicalTrials.gov. Generated by ClinicalTrialsFinder.org.