

# Effects of Anakinra in Subjects With Corticosteroid-resistant/Intolerant Meniere's Disease and Autoimmune Inner Ear Disease

NCT03587701

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Status	RECRUITING
Phase	Phase 2
Sponsor	Northwell Health
Enrollment	57 participants

## Key Eligibility Criteria

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### Inclusion (10)

- meet diagnostic criteria for Autoimmune Inner Ear Disease (AIED) with active deterioration in one ear as defined below
- SNHL of greater than 30dB at one or more frequencies in the active ear. The contralateral ear may have any hearing threshold that is either stable or worsening, but may not exhibit improvement in response to corticosteroids even if the more active ear declines. Active deterioration is defined as a 15dB decline at one frequency (excluding 250 or 8kHz as a sole indicator) on their audiogram, or 10dB at 2+ frequencies developing in  $\geq$  or equal 3 days but  $<$  or equal 90 days, or if the hearing loss evolved in less than 3 days, the patient displayed features suggestive of an autoimmune disorder
- Capable of understanding and giving informed consent
- Have 2 sequential audiograms following the decline in hearing  $\geq$  or equal 28 days apart with no demonstrable improvement in hearing following corticosteroid therapy ( $<$  or equal 5dB of improvement at any individual frequency (250, 500, 1000, 2000 and 4000Hz) and  $<$  12% improvement in WRS)
- Patients must have been treated with oral or IT prednisone with no demonstrable improvement or attempted to be treated and deemed intolerant. Steroid intolerance is defined as unable or unwilling to take corticosteroids because of a prior untoward effect or a current medical condition that would negatively be impacted by steroid use

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

### Exclusion (21)

- Evidence of retrocochlear pathology (vestibular schwannoma) or inner ear malformation (Mondini Malformation or Enlarged Vestibular Aqueduct) based on imaging
- Prior treatment with gentamicin for Meniere's Disease
- Most recent decline in hearing occurring  $\geq$  90 days prior to trial enrollment
- Positive test for Muckle-Wells mutation
- Concurrently receiving methotrexate, TNF-antagonist therapy or any other immunosuppressive therapy

... and 16 more (see full listing online)

## Locations (1 total)

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Northwell Health, Hearing & Speech Center, New Hyde Park, New York, United States

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<https://clinicaltrials.gov/study/NCT03587701>

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