Phase 1 Study of SPT-2101 Given as a Single Intratympanic Injection in Subjects with Unilateral Meniere's Disease

ACTRN12621000964819

Status	RECRUITING
Phase	Phase 1
Sponsor	Spiral Therapeutics Australia Pty Ltd
Enrollment	40 participants

Plain Language Summary

This Phase 1 study is testing a new drug called SPT-2101 for Meniere's disease — a chronic inner ear condition that causes sudden, unpredictable episodes of severe vertigo (spinning dizziness), hearing loss, tinnitus, and a feeling of fullness in the ear. Meniere's can be debilitating and is currently managed with dietary changes, medications, and — in severe cases — injections into the ear or surgery. SPT-2101 is injected directly into the middle ear (intratympanic injection) and is designed to target the underlying fluid imbalance thought to cause symptoms.

Participants will first complete a four-week diary to document baseline vertigo episodes. Eligible participants will then receive either SPT-2101 or a placebo saline injection into the affected ear in a single dose, and will be followed up for approximately six months with monitoring visits. Some participants may be offered the active treatment after 85 days if they were in the placebo group.

To be eligible, you must be aged 18 to 85 with a confirmed diagnosis of unilateral Meniere's disease (affecting one ear only), have active vertigo episodes lasting 20 minutes or more, and have documented hearing loss. People with active ear infections, perforated eardrums, or other causes of vertigo (like benign paroxysmal positional vertigo) are not eligible. The study is run by Spiral Therapeutics Australia.

Key Eligibility Criteria

Inclusion (5)

- Age 18 years to 85 years (inclusive) at the time of screening
- Provides written informed consent prior to participation in any study procedure
- Has a diagnosis of unilateral Definite Meniere's disease defined by the Classification Committee of the Bárány Society or the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)
- Self-reports active, definitive vertigo (lasting 20 minutes or more) in the 3 months prior to screening and records 2 or more Definitive Vertigo Days in the lead-in period.
- Has documented acquired asymmetric sensorineural hearing loss, as reported by the patient or documented by audiometric testing

Exclusion (5)

- Ongoing chronic inflammatory or infectious middle ear disease
- Active infection in the ear, sinuses, or upper respiratory system
- Current tympanic membrane perforation, including ventilation tube, in the affected ear.
- Active benign paroxysmal positional vertigo (BPPV) symptoms
- History of superior canal dehiscence

Locations (4 total)

Linear Clinical Research - Nedlands, NSW,SA,WA,VIC, Australia

Flinders Medical Centre - Bedford Park, NSW,SA,WA,VIC, Australia

The Royal Victorian Eye and Ear Hospital - East Melbourne, NSW,SA,WA,VIC, Australia

... and 1 more locations