

A Treatment for a Form of Age-Related Central Auditory Processing Disorder Consisting of Clemastine Fumarate Plus Engineered Sound

NCT07304024

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	University of Colorado, Denver
Enrollment	344 participants

Key Eligibility Criteria

Inclusion (9)

- Male or female between 45 and 65 years old (middle aged) at the screening/enrollment visit (Visit 1).
 - Written informed consent obtained from the subject and ability for the subject to comply with the requirements of the study.
 - Documentation of no more than a mild high-frequency hearing sensitivity loss and normal middle-ear function will be obtained using standard audiometric equipment with measurements done by an audiologist; Specifically, testing will show:
 - bilateral hearing thresholds ≤ 20 dB HL at audiometric frequencies from 250 Hz to 4000 Hz inclusively, with no air-bone gaps > 10 dB.
 - symmetrical hearing thresholds between the ears through 8000 Hz, defined as ≤ 20 dB difference at any single audiometric frequency or ≤ 15 dB difference at 2 or more contiguous frequencies.
- ... and 4 more (see full listing online)

Exclusion (29)

- Any subjects who do not fall under the criteria defined above.
 - Any of the following conditions which are listed as contraindications or warnings for use of the clinical trial drug (from labeling):
 - Known sensitivity to clemastine fumarate or other antihistamines of similar composition
 - Pregnancy or nursing mother as determined objectively with a urine pregnancy test
 - Lower respiratory tract disease including asthma, or breathing difficulties such as emphysema or chronic bronchitis
- ... and 24 more (see full listing online)

Locations (1 total)

University of Colorado Anschutz Medical Center, Aurora, Colorado, United States