A Phase I/II Clinical Trial with SENS-501 in Children Suffering from Severe to Profound Hearing Loss Due to Otoferlin (OTOF) Mutations

NCT06370351

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Sensorion
Enrollment	12 participants

Key Eligibility Criteria

Inclusion (6)

- Children (male or female) e 6 to d 31 months at the time of inclusion
- Severe to profound hearing loss assessed by auditory brainstem response (ABR)
- Biallelic mutation in the Otoferlin gene
- Presence of Otoacoustic emissions (OAEs)
- Documented normal cochlea and internal auditory canals

... and 1 more (see full listing online)

Exclusion (7)

- History of chronic, acute, or major disease, or unspecified reasons, that in the opinion of the Investigator, makes the participant unsuitable for participation in the study or constitutes an unacceptable risk.
- Have been dosed in a previous gene therapy clinical trial
- Patients with a prior or current cochlear implant
- Any contraindication to the surgery determined by the surgeon or anesthesia determined by the anesthesiologist, or designee, or history of therapy known as ototoxic (e.g., cisplatin, high dose and long treatment with aminoglycosides, etc.) for an extended period (more than 2 weeks).
- Participation in any other interventional clinical trial

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

Locations (2 total)

Childrens Hospital Westmead, Westmead, Australia
Hopital Necker Enfants Malades, Paris, France