Pediatric Expansion Study of the Sentio System

NCT06976086

Status	RECRUITING
Phase	Not Applicable
Sponsor	Oticon Medical
Enrollment	50 participants

Key Eligibility Criteria

Inclusion (9)

- Signed Informed Consent Form (depending on age of child, signed by parent or legal guardian and child)
- Subject aged 3 to 11 years
- Subject with:
- conductive or mixed hearing losses with pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2 and 3 kHz) of the indicated ear better than or equal to 45 dB HL.
- OR subject who has a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e. SSD). The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should then be better than or equal to 20 dB HL (measured at 0.5, 1, 2 and 3 kHz) 3.3 OR subject indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.

... and 4 more (see full listing online)

Exclusion (16)

- Medical condition that contraindicates implant surgery or anesthesia as judged by the investigator.
- Untreated ongoing middle ear infection at the time of surgery.
- Known or suspected contact allergy to silicone or other material used in the Sentio system.
- Known condition that could jeopardize wound healing and skin condition, e.g. uncontrolled diabetes over time, as judged by the investigator.
- Known skin or scalp conditions that may preclude attachment or interfere with the usage of the sound processor.

... and 11 more (see full listing online)

Locations (8 total)

University Medical Center Groningen, Groningen, Netherlands
Radboud University Medical Center, Nijmegen, Netherlands
Hospital Universitario de Donostia, San Sebastián, Spain
... and 5 more locations