

Evaluation of Performances, Clinical Benefits and Safety of the 'Audiocap' Connected Hearing Rehabilitation Device for Improving Audibility in Hearing-impaired People in the Context of CE Marking - AUDIOCAP-2

NCT07252492

Status	RECRUITING
Phase	Not Applicable
Sponsor	Archean Technologies
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (5)

- Subjects presenting one or more of the following criteria: a. Subject with mild to moderate hearing loss (20dB to 50dB average at 500, 1000, 2000, and 4000 Hz) in the better ear according to WHO standards, / b. Subject with a speech reception threshold (SRT) in quiet exceeding 30dB, corresponding to the minimum speech level required to achieve 50% recognition in silence (HAS eligibility criteria for hearing aid reimbursement), / c. Subject with significant degradation of speech intelligibility in noise, defined as a speech-to-noise ratio (SNR) deviation greater than 3dB compared to normative reference values (HAS eligibility criteria for hearing aid reimbursement), / d. Subject with high-frequency hearing loss greater than 30dB from 2000 Hz onwards, associated with a speech reception threshold exceeding 30dB in quiet and/or a significantly degraded speech intelligibility in noise (HAS eligibility criteria for hearing aid reimbursement).
- Subjects eligible for first hearing aid.
- Subjects over 18 years of age. French-speaking subjects.
- \. Subjects affiliated with a social security scheme. 6. Subjects who are not subject to another medical option, without external pathology and excluding implants.
- \. Subjects who have signed an informed consent. 8. Subjects available for the study.

Exclusion (17)

- Subject deprived of his/her liberty by a judicial or administrative decision
- Subject with severe psychiatric disorder
- Subject admitted to a health or social care establishment
- Subject not able to give consent
- Adults under guardianship or trusteeship.

... and 12 more (see full listing online)

Locations (4 total)

Hôpital Edouard Herriot, Lyon, France, France
Clinique de l'Oreille, Paris, France, France
Hôpital Lariboisière (APHP), Paris, France, France
... and 1 more locations

<https://clinicaltrials.gov/study/NCT07252492>

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