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The impact of cochlear implants on listening effort and fatigue

Submission date
03/12/2025

Recruitment status
Recruiting

Registration date
31/12/2025

Overall study status
Ongoing

Last Edited
31/12/2025

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Individuals with hearing loss have increased listening effort relative to normal hearing listeners and subsequently suffer from increased listening fatigue. Listening effort has complex aspects involving the use of mental resources to overcome obstacles to pursue listening goals, while constantly weighing whether the effort is worth the cognitive demands. With the lack of consistency across studies and widely varied measures in study populations, drawing conclusions about the impact of cochlear implant (CI) on listening effort is difficult, particularly for studies assessing the impact that listening effort has on fatigue in CI users. There are few studies investigating the impact that increased listening effort has on fatigue in CI users, with complex models of listening related fatigue not adequately captured by current measures. The use of questionnaires assessed in real world settings, including difficult listening environments, is important for understanding listening effort. This study aims to test whether subjective listening effort and general fatigue in everyday life are reduced following cochlear implantation in adults aged 18 or over with severe to profound hearing loss.

Who can participate?
Adult patients aged 18 or over with severe to profound hearing loss eligible for a CI based on French criteria and receiving their first Nucleus® CI.

What does the study involve?
Self-reported questionnaires of listening effort, general fatigue and overall benefit, reporting the everyday experiences in a home environment.

What are the possible benefits and risks of participating?
Potential benefits associated with participation in this study include helping to find better treatments and therapies and/or diagnostic tests in the area of hearing loss or related conditions and allowing a greater understanding of the obstacles faced by CI users regarding listening effort and fatigue in real world scenarios. As a non-interventional study, risks are expected to be very low. However, consideration will be given to psychological events such as anxiety or depression that may result from participation.

Where is the study run from?
-Hôpital de Hautepierre, Strasbourg, France
-Hôpital Robert Debre, Reims, France
-CHU de Dijon, Dijon, France

When is the study starting and how long is it expected to run for?
November 2025 to November 2027

Who is funding the study?
Cochlear France

Who is the main contact?
Prof. Marc Labrousse

Contact information

Type(s)
Public

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None PRS Specialist

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Additional identifiers

Study information

Scientific Title
The impact of cochlear implants on listening effort and fatigue: a post-market observational study

Acronym
ILCI

Study objectives
The overall aim of the study is to evaluate whether subjective listening effort and general fatigue in everyday life are reduced following cochlear implantation in adults with severe to profound hearing loss receiving cochlear implants under standard indications.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/06/2025, Comité de Protection des Personnes Est III (CHRU de Nancy, Rue du Morvan, VANDOEUVRE-LES-NANCY, 54511, France; +33 3 8315 4324; cppest.3@chru-nancy.fr), ref: 2025-A00953-46

Primary study design
Observational

Secondary study design
Multi-centre observational study

Study type(s)

Health condition(s) or problem(s) studied
Adults aged 18 or over with severe to profound hearing loss

Interventions
In this observational study, subjects are recruited consecutively as part of the clinical routine. Subject data will be collected pre implant and at 1- and 6-months post implant to record any changes over time in the primary outcome measures. The primary and secondary measures are self-reported questionnaires of listening effort, general fatigue, and overall benefit, reporting the everyday experiences in a home environment. Listening effort will be assessed using the Listening Effort Assessment Questionnaire (EAS). Fatigue will be assessed using the generalised Multidimensional Fatigue Inventory (MFI). Health benefits will be assessed using the Glasgow Benefit Inventory (GBI). The total period of participation for each subject will be approximately 9 months. The study will end at the 6-month routine clinical follow up appointment or at subject withdrawal.

Intervention Type
Other

Primary outcome(s)
1. Comparison of every day subjective listening effort measured using the Extended Effort Assessment Scale (EEAS) at pre-implantation and 6 months post-activation

2. Comparison of general fatigue before and after cochlear implantation measured using multidimensional Fatigue Inventory 20 question version (MF120) at pre-implantation and 6 months post-activation

Key secondary outcome(s))
1. Measure early changes in listening effort and fatigue measured using EEAS for listening effort and MF120 for fatigue measures at 1-month post-activation

2. Report the self-reported health benefits of cochlear implant measured using the Glasgow Benefit Inventory Five Factor (GBI-5F) at 6-months post-activation

Completion date
30/11/2027

Eligibility

Key inclusion criteria
1. Adult patients aged 18 or over with severe to profound hearing loss eligible for a CI based on French criteria and receiving their first Nucleus CI.
2. Native French speaker.
3. Willing and able to participate in all the procedures.
4. Have no opposition to their data being collected, analysed and anonymously reported in a publication.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Unable or unwilling to comply with the requirements of the clinical investigation as determined by the Investigator.
2. Investigator site personnel directly affiliated with this study and/or their immediate families; immediate family is defined as a spouse, parent, child, or sibling.
3. Cochlear employees or employees of Contract Research Organisations or contractors engaged by Cochlear for the purposes of this investigation.
4. Current participation, or participation in an interventional clinical study/trial in the past 30

days, involving an investigational drug or device (unless the other investigation was/is a Cochlear sponsored investigation and determined by the investigator or Sponsor to not impact this investigation).

Date of first enrolment
30/11/2025

Date of final enrolment
30/07/2027

Locations

Countries of recruitment
France

Study participating centre
Hôpital de Hautepierre
Avenue Molière
Strasbourg
France
67098

Study participating centre
Hôpital Robert Debre
Rue du général koenig
Reims
France
51092

Study participating centre
CHU de Dijon
1 bd Maréchal de Lattre de Tassigny
Dijon
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Sponsor information

Organisation
Cochlear (France)

ROR
https://ror.org/00zhfb561

Funder(s)

Funder type

Funder Name
Cochlear France

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
France

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available