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Comparing cochlear implants with hearing aids in adults with severe hearing loss

Submission date
30/09/2021

Recruitment status
Recruiting

Registration date
01/10/2021

Overall study status
Ongoing

Last Edited
23/07/2025

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
In the UK, cochlear implants are provided to some people with severe or profound hearing loss who do not get enough benefit from their hearing aids. Cochlear implants can improve their ability to recognise sounds and understand speech. Currently, only these adults are offered a cochlear implant on the NHS.
This study aims to find out whether some adults who are not currently offered a cochlear implant on the NHS would benefit more from a cochlear implant than they would from using hearing aids alone. These people are those whose hearing or speech test results are just outside of the range that would make them eligible for a cochlear implant on the NHS. It is not known if cochlear implantation is a good treatment option compared to hearing aids for these people.

Who can participate?
Patients aged 18 years and over with severe hearing loss

What does the study involve?
Participants are randomly allocated to receive a cochlear implant or new hearing aids (or can choose to continue to wear their own). The researchers will compare how well the two groups can understand speech after 9 months.

What are the possible benefits and risks of participating?
Both treatments in this study are already available as standard NHS procedures but only for people who meet the current NHS eligibility criteria. Like any treatment, both have possible disadvantages and risks. For the cochlear implant group some risks following surgery may include potential loss of the natural hearing the patient had before (meaning that the patient might not be able to go back to using a hearing aid if they weren't happy with the cochlear implant), temporary facial weakness, tinnitus, meningitis, pain and discomfort, as well as the normal risks associated with surgery and general anaesthesia. For the hearing aid group the risks may include pain and discomfort from the use of the new hearing aids, ear infections and exacerbation of eczema.

Where is the study run from?
Nottingham Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
January 2021 to Febraury 2029

Who is funding the study?
Cochlear Ltd (Australia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
297574

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 50095, IRAS 297574

Study information

Scientific Title
The COACH trial: A randomised controlled trial of cochlear implantation versus hearing aids in adults with severe hearing loss

Acronym
COACH

Study objectives
Primary objective:
To evaluate the effect of cochlear implantation on speech understanding in quiet in comparison to the use of acoustic hearing aids (HAs) in adults with severe hearing loss whose audiometric thresholds and/or speech perception scores fall outside current UK candidacy criteria for cochlear implantation (as per NICE guidance TA566).

Secondary objectives:
1. To evaluate the effect of cochlear implantation on broader hearing-related outcomes including speech understanding in noise, difficulties with listening in everyday environments, listening-related fatigue, and tinnitus in comparison to those using acoustic HAs
2. To evaluate the effect of cochlear implantation on broader health and well-being outcomes including mood, hearing-related quality of life, and health-related quality of life in comparison to those using acoustic HAs
3. To assess the safety of cochlear implantation and acoustic HAs. To characterise the duration and nature of cochlear implant (CI) and HA use

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/09/2021, South West – Frenchay Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 104 8106; frenchay.rec@hra.nhs.uk), REC ref: 21/SW/0098

Study design
Randomized; Interventional; Design type: Treatment, Device, Surgery

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe hearing loss

Interventions
This trial aims to find out whether a certain group of adults who are not currently offered a cochlear implant on the NHS would benefit more from a cochlear implant than they would from using hearing aids. These people are those whose hearing or speech test results are just outside of the range that would make them eligible for a cochlear implant on the NHS. In the trial, some people will receive a cochlear implant, and some will receive new hearing aids (or can choose to continue to wear their own). The researchers will compare how well the two groups can understand speech after 9 months.

Participants will be individually randomised on a 1:1 ratio, minimised by trial site, severity of tinnitus and baseline AB word test phoneme score. The randomisation system is via REDCap, a browser-based data capture system.

Intervention: Unilateral (in one ear) cochlear implantation and offer of a new acoustic hearing aid or optimisation of current hearing aid in the other ear.

Comparator: Offer of new bilateral (both ears) acoustic hearing aids or optimisation of current hearing aids. Participants will be followed up at 1, 3, 6 and 9-months post treatment activation. The primary outcome will be collected at the 9-month timepoint as clinicians report that the identification of words following cochlear implantation stabilises between approximately 3-6 months and therefore assessment at 9 months will ensure stabilised performance has been reached.

Qualitative Study: Process Evaluation
Within this trial the researchers will deliver a process evaluation by talking to different groups of participants and healthcare workers involved in the trial about their feelings and experiences, to better understand the results of the COACH trial and inform future implementation.

This will involve the following:
1. 30 participants randomised to the intervention (CI arm) who will be interviewed at two timepoints: post randomisation but before cochlear implantation and at the 9 month follow up appointment following first treatment activation
2. 15 participants randomised to the comparator (HA) arm who will be interviewed once, within 6 weeks of randomisation
3. 20 healthcare professionals who are participating in the COACH trial and their interview will take place in the final months of the trial
4. 6 individuals that declined when invited to participate in the COACH trial who will be interviewed once, within 6 weeks of their recruitment approach
All interviews will be semi-structured with open questions, will be audio-recorded and undertaken face-to-face where possible.

Recruitment Intervention
As equipoise is highly important in the COACH trial, and many audiology staff members will be inexperienced in research processes and regulations, recruitment and consent conversations between the healthcare staff and potential participants will be monitored and reviewed. This is to ensure the information is explained well to potential participants and that the issues of equipoise are covered and to make any improvements or provide extra training to the healthcare staff is necessary. A member of the COACH trial team from the University of Nottingham will observe the conversations, either in person or via video call, and may audio-record some conversations, with permission from both the potential participant and the healthcare staff.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cochlear implant, hearing aids

Primary outcome(s)
The perception of phonemes as quantified by the phoneme score on the AB word test (a measure of speech understanding) presented at 60 dBA in the best-aided condition (i.e., using the devices that the participant considers will help them hear as well as possible); Timepoint(s): 9 months post first treatment activation (intervention arm: first CI activation; comparator arm: first HA fitting/optimisation) measured by independent blinded assessors.

Key secondary outcome(s))
1. Phoneme perception measured using the AB Word test at 60 dBA; Timepoint(s): 3, 6 and 9 months following first treatment activation, measured by the audiologist
2. Word perception measured using the AB Word test at 60 dBA; Timepoint(s): 3, 6 and 9 months following first treatment activation
3. Phoneme perception measured using the AB Word test at 70 dBA; Timepoint(s): 9 months following first treatment activation
4. Word perception measured using the AB Word test at 70 dBA; Timepoint(s): 9 months following first treatment activation
5. Sentence perception in quiet measured using the BKB sentence test at 70 dBA; Timepoint(s): 3, 6 and 9 months following first treatment activation
6. Sentence perception in noise measured using the Adaptive BKB sentence test; Timepoint(s): 3, 6 and 9 months following first treatment activation
7. Speech sound discrimination measured using the Phoneme discrimination test; Timepoint(s): 9 months following first treatment activation
8. Device usage measured using device logging; Timepoint(s): 3, 6, and 9 months
9. Audiometric thresholds (aided and unaided) measured using clinical equipment; Timepoint(s): On the day of treatment activation and at 3, 6 (unaided only) and 9 months following first treatment activation
10. Difficulty with listening measured using the 12-item Speech Spatial and Qualities of listening scale (SSQ12); Timepoint(s): 1, 3, 6, and 9 months post first treatment activation
11. Listening effort and fatigue measured using the Effort Assessment Scale (EAS), Fatigue Assessment Scale (FAS), Listening Effort Questionnaire-Cochlear Implant (LEQ-CI); Timepoint(s): 1, 3, 6, and 9 months post first treatment activation
12. Tinnitus severity measured using the Tinnitus Functional Index (TFI); Timepoint(s): 1, 3, 6, and 9 months post first treatment activation
13. Tinnitus loudness measured using the Visual Analogue Scale of Loudness (VAS-L); Timepoint (s): Immediately before and after first treatment activation and at 1, 3, 6, and 9 months post first treatment activation
14. Mood measured using the Hospital Anxiety and Depression Scale (HADS); Timepoint(s): 1, 3, 6, and 9 months post first treatment activation
15. Hearing-specific quality of life measured using the Nijmegen Cochlear Implant Questionnaire (NCIQ), York Binaural Hearing-Related Quality of Life (YBHRQL), Hearing Handicap Inventory for Adults (HHIA); Timepoint(s): 1, 3, 6, and 9 months post first treatment activation
16. Global ratings of change in hearing and quality of life measured using validated patient-reported outcome measures (PROMs); Timepoint(s): 1, 3, 6, and 9 months post first treatment activation

Completion date
28/02/2029

Eligibility

Key inclusion criteria

1. Adults aged 18 years or older
2. Patients with a severe sensorineural hearing loss in both ears (pure-tone audiometric threshold equal to or greater than 70 dB HL) at two or more frequencies (500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids
3. Patients with appropriate hearing aid devices and prescriptions, with a minimum of 3 months having elapsed since any change in devices or prescriptions
4. Patients with a phoneme score <60% on the AB Word test when tested in quiet at 70 dBA with acoustic hearing aids
5. Patients in whom history, examination and pre-operative imaging suggests a healthy middle ear in the ear to be implanted, and a structurally normal and fully patent cochlea with no evidence of a widened vestibular aqueduct
6. Patients for whom unilateral cochlear implantation is not recommended by NICE either because they do not meet the definition of severe to profound deafness (pure-tone audiometric threshold equal to or greater than 80 dB HL at two or more frequencies between 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz), or because they meet the definition of adequate benefit from HAs (a phoneme score >= 50% on the AB Word test when tested in quiet at 70 dBA with acoustic hearing aids), or both (as per recommendation 1.5, NICE TA566)
7. Patients who are capable of speaking and understanding the English language
8. Patients who are capable and willing to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patient characteristics falling outside the indications for use of the trial devices as per their CE marking
2. Inability to undergo speech perception testing and/or inability of audiologist to obtain an accurate measurement of speech perception abilities
3. Patients who would not be able to adhere to trial procedures or complete the trial questionnaires
4. Patients whose hearing loss is suspected or confirmed to be wholly or partly unexplained by anatomic or physiologic abnormalities (non-organic hearing loss)
5. Patients who have a congenital severe hearing loss
6. Any known factor that may restrict the full insertion of the electrode array
7. Patients with any known contraindication for cochlear implantation
8. Patients whose primary concern is the suppression of tinnitus
9. Patients in whom cochlear implantation would present an unacceptable risk to balance function
10. Any serious concerns about medical fitness for surgery or cochlear implantation

11. Participation in other research related to hearing loss while participating in the trial (i.e., until collection of primary outcome), including research that involves any changes to or use of hearing devices, changes to hearing care/management, or duplication of trial outcome assessments

Date of first enrolment
04/10/2021

Date of final enrolment
30/11/2026

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre

Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
St George's Hospital
Blackshaw Road
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London
United Kingdom
SW17 0QT

Study participating centre
Cardiff & Vale University LHB
Woodland House
Maes-Y-Coed Road
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CF14 4HH

Study participating centre
University College London Hospital
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
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United Kingdom
SE1 7EH

Study participating centre
The James Cook University Hospital
Marton Road

Middlesbrough
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TS4 3BW

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Industry

Funder Name
Cochlear

Alternative Name(s)
Cochlear Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Australia

Results and Publications

Individual participant data (IPD) sharing plan
In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Research Code of Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the trial. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the trial records, a second person will be nominated to take over this responsibility. The TMF and trial documents held by the Chief Investigator and the NCTU on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of

Nottingham. This archive shall include all trial databases and associated meta-data encryption codes. All trial staff and investigators will endeavour to protect the rights of the trial's participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Participant information sheet	version 1.8	11/01/2024	16/05/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 6.2	20/03/2024	16/05/2024	No	No
Protocol file	version 6.3	15/05/2024	20/08/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes