ISRCTN13600782 https://doi.org/10.1186/ISRCTN13600782

New tests for remote monitoring of cochlear implants

Submission date
13/07/2016

Recruitment status
No longer recruiting

Registration date
22/09/2016

Overall study status
Completed

Last Edited
17/01/2022

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A cochlear implant is a surgically implanted electronic device that provides a sensation of hearing to adults and children with severe to profound deafness. About 1,200 people receive a cochlear implant in the UK each year. At the moment people with implants need to come back to their cochlear implant centre every year for checks. There are only around 20 cochlear implant centres in the UK, so people can live several hours away. Coming to the cochlear implant centre can be expensive for some people, and can mean time off work for people using implants and their families. We would like to have some tools that people using implants could have at home so they could send the results to the clinician to see if they need to come to the centre or not. It could also help clinicians decide how long an appointment should be. We have developed a new set of tests that could be used to work out if someone using a cochlear implant needs to come to the cochlear implant centre. The tests are very similar to those done in the clinic: a hearing test, a speech understanding test using numbers, checking the internal implant, downloading the current settings, and some questionnaires. Some will be done on an iPad and some using the usual software the audiologists use. We want to know how people using implants feel about these tests. We will also ask clinicians if there is anything else they need in order to decide if someone needs to the cochlear implant centre or not.

Who can participate?
Adults or children (aged 4 and over) who have used a cochlear implant (a CP900 series sound processor and a CI500, CI24RE, Nucleus 24 Series or CI422 internal implant) for at least 3 months, and who have a routine clinical appointment scheduled during the study period.

What does the study involve?
The study involves the participants undergoing the new tests before their appointment with the audiologist. The audiologist then looks at the results to see if they give enough information to decide what the patient needs help with. They then attend the usual appointment with the audiologist. All study testing takes place in the hour before the appointment. The new tests are:
1. Digit Triplet Test: a hearing test listening to numbers and repeating them
2. Aided thresholds: listening and responding to quiet beeps, like in the clinic
3. Telemetry: checking of the internal implant, like the audiologist does in clinic, including downloading settings from the speech processor, for example how the patient has worn the

processor. The audiologist always does this in clinic too
4. Filling in a questionnaire about how the patient/carer is feeling about their hearing, how much the processor is being used, and if there is anything the patient needs help with
5. The tester takes a photo of the implant site behind the ear
The audiologist then looks at these results and fills in a questionnaire about whether the results are enough to decide what sort of appointment (if any) is needed.

What are the possible benefits and risks of participating?
There will not be any direct benefits to the participant. However, it may enable us to improve our service for people with cochlear implants in the future. New speech testing software will be used to deliver the sounds for the tests. As with any software, there is a small risk of hearing sounds that are uncomfortably loud. If this happens, the participant can stop the sound immediately by taking off the speech processor coil/headpiece. The participant can stop the project at any point, without having to say why.

Where is the study run from?
The project is led by University of Southampton Auditory Implant Service. The other centres are: The Emmeline Centre for Hearing Implants, Cambridge; Scottish Cochlear Implant Programme, Kilmarnock; Nottingham Auditory Implant Programme, Nottingham.

When is the study starting and how long is it expected to run for?
May 2016 to May 2017

Who is funding the study?
Cochlear Ltd (Australia)

Who is the main contact?
Dr Helen Cullington

Contact information

Type(s)
Public

Contact name
Dr Helen Cullington

ORCID ID
https://orcid.org/0000-0002-5093-2020

Contact details
University of Southampton Auditory Implant Service
Highfield
Southampton
United Kingdom
SO17 1BJ

Additional identifiers

Protocol serial number

CLTD-5654

Study information

Scientific Title
Evaluation of test battery for remote monitoring of cochlear implants

Study objectives
Primary: With the test battery the clinician is able to detect all issues that might need intervention.
Secondary: The number of recipients or parents/carers who find remote monitoring an acceptable method to determine the need for a clinical visit will be greater than the number who do not.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. East of England - Cambridgeshire and Hertfordshire Research Ethics Committee, 31/05/2016, ref: 16/EE/0177
2. Health Research Authority, 03/11/2016, ref: 16/EE/0177

Study design
Unblinded prospective multicentre investigation using repeated-measures single-subject design conducted in one session only

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Severe to profound deafness

Interventions
The following procedures that are part of the remote monitoring test battery will be conducted with the patient using a cochlear implant just before they see the clinician or their standard appointment:
1. Digit Triplet Test
2. Aided thresholds using iPad
3. Picture of scalp over implant site
4. Implant telemetry measurements
5. Completion of a questionnaire (by parent/carer in case of paediatric recipients) that includes questions regarding any sound quality issues they are experiencing and any other issues that might require clinical intervention.
6. Collection of processor usage and environment information using datalogs or by questionnaire.

The clinician will be asked to review the above mentioned data collected and will report if the data is sufficient to determine the need for intervention, and what type of intervention is required. This information will be captured in a questionnaire.

The patient will then have the standard clinical session. All tasks completed in the clinical session will be recorded in a clinician questionnaire. The clinician will report any interventions conducted in the clinical session that were in addition to those determined during the review of test battery data. The sources of information that helped the clinician to determine the need for the additional interventions will also be recorded in the questionnaire.

Intervention Type
Other

Primary outcome(s)
Whether the test battery provides sufficient information for the clinician to determine if the recipient needs any intervention, assessed through the Clinician Questionnaire at the single study visit

Key secondary outcome(s))
Secondary endpoint
The acceptance of the concept of remote monitoring for recipients or parent/carers, assessed through the Recipient/Parent Questionnaire at the single study visit

Exploratory endpoint
Feedback from clinicians regarding any additional clinical metrics that will increase the acceptability of the test battery for remote monitoring captured; collected at the single study visit

Completion date
28/02/2017

Eligibility

Key inclusion criteria
1. Adults (>18 years) using cochlear implants or children (>4 years) using cochlear implants
2. Implanted with the CI500 series, CI24RE, Nucleus 24 Series or CI422 cochlear implants
3. User of commercially available CP900 series sound processor
4. At least 3 months experience with the cochlear implant
5. Ability to complete closed set speech perception of numbers 0 to 9 in the language used for the Digit Triplet Test (English)
6. Willingness to participate in and to comply with all requirements of the protocol
7. Routine clinical appointment scheduled during the study period

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 years

Sex
All

Total final enrolment
93

Key exclusion criteria
1. Adults or parents/carers with limited English that would prevent completion of questionnaires
2. Nucleus 22 cochlear implant recipients
3. Additional handicaps that would prevent participation in evaluations
4. Unrealistic expectations on the part of the subject, regarding the possible benefits, risks and limitations that are inherent to the procedures

Date of first enrolment
31/05/2016

Date of final enrolment
28/02/2017

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
University of Southampton Auditory Implant Service
Highfield
Southampton
United Kingdom
SO17 1BJ

Study participating centre
The Emmeline Centre for Hearing Implants
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Scottish Cochlear Implant Programme
Kilmarnock
United Kingdom
KA2 0BE

Study participating centre
Nottingham Auditory Implant Programme
Nottingham
United Kingdom
NG1 5DU

Sponsor information

Organisation
Cochlear Ltd (Australia)

ROR
https://ror.org/04hvmsy06

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
Not provided at registration.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/08/2021	17/01/2022	Yes	No
Basic results		20/11/2020	20/11/2020	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet		14/09/2016	28/09/2016	No	Yes
Participant information sheet		14/09/2016	28/09/2016	No	Yes
Participant information sheet		14/09/2016	28/09/2016	No	Yes
Participant information sheet		14/09/2016	28/09/2016	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes