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The effect of surgical approach on hearing preservation in cochlear implant surgery

Submission date
12/02/2019

Recruitment status
Suspended

Registration date
15/02/2019

Overall study status
Completed

Last Edited
08/03/2021

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
A cochlear implant is a device that is inserted into the cochlea (the hearing organ) to stimulate it electrically and provide the sensation of sound. It is used in people who have severe hearing loss at higher frequencies. Higher frequencies tend to be important for hearing speech. Some people with hearing loss like this still have lots of hearing at lower frequencies. This can be very important, particularly with things like hearing music. The question we want to answer is how can we do a cochlear implant operation while keeping as much of the low-frequency hearing as possible.
The two ways that cochlear implants are put into the inner ear are called ‘round window’ and ‘cochleostomy’. A ‘round window’ insertion involves drilling around a soft opening of the cochlea and then opening this soft area. It has the advantage of going into what is almost a ‘natural opening’ in the ear. However, it can be difficult to reach, and it might be that by changing the ‘natural opening’ of the ear, we also change the way sound works in the ear. A ‘cochleostomy’ involves using a small drill to make a hole in the side of the cochlea, and placing the cochlear implant through the hole. This has the advantage of being more straightforward to access and going directly to the hearing parts of the cochlea, but as it does not go through a ‘natural opening’ it can be more difficult to find the best part of the hearing organ to put the implant. Both techniques are very commonly used throughout the UK, and indeed across the world, and whichever technique the patient has will allow him to use a cochlear implant normally.

Who can participate?
Anyone who is having an implant of Med-El Flex28, cochlea Co.CI522 or Advanced bionic HiFocus 1j electrode array, who meets the inclusion criteria can participate.

What does the study involve?
The study involves being randomised to receive one or other type of cochlear implant insertion surgery followed by a number of hearing related tests over the next year to assess the effects of the implant. Patients would be assessed frequently during your first year, all of these assessments are part of routine practice in our centre for patients who receive cochlear implants. For the duration of your first year with a cochlear implant, we will use the data from

the patient's appointments to determine how much the cochlear implant is helping your hearing. After this point, the involvement with the study will end, but patient's ongoing cochlear implant care will continue as it would if you were not part of the study.

What are the possible benefits and risks of participating?
The great majority of patients who undergo implantation benefit significantly from the improved hearing that implants can provide to those with severe and profound hearing loss. However, the insertion of cochlear implants does carry risks. These risks are small, and complications associated with cochlear implants are rare. Your involvement in this study will not affect these risks. Risks associated with the operation include infection, bleeding, scarring, dizziness, device failure, loss of residual hearing, and very rarely taste disturbance or weakness of one side of the face (when they do occur these are usually temporary).
These risks will be the same whether the subject chooses to enter the study or not. The procedure patient undergoes, whichever technique is used, will be a routine cochlear implant procedure.

Where is the study run from?
The Royal National Throat Nose and Ear Hospital (RNTNEH), University College Hospitals NHS Foundation Trust (UCLH), 330 Grays Inn Road, London, WC1X 8DA

When is the study starting and how long is it expected to run for?
It is expected that the study will last for 2years starting from recruiting the first participant in March 2019. The study will investigate the outcomes of patients during their regular follow-up appointment during the first year of their treatment.

Who is funding the study?
The study is being funded by Med-El GmbH, cochlear implant manufacturer.

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
63284

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Protocol number:16/0551, IRAS project ID:63284

Study information

Scientific Title
Round window versus cochleostomy electrode array insertion with lateral wall atraumatic electrode: a prospective randomised clinical study

Study objectives

This study will investigate the effect of surgical approach (round window versus cochleostomy electrode array insertion) on hearing preservation in cochlear implant surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/09/2018: London - Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, Barlow House 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ; 0207 104 8345; nrescommittee.london-bloomsbury@nhs.net), ref:18/LO/1405

Study design
This is a double-blind prospective randomized controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Hearing loss

Interventions
The intervention procedures are cochleostomy and round window insertion of a cochlear implant. Both surgical approaches are part of clinical standard of care and routinely practiced in the UK and abroad. These will be undertaken at the time of surgical cochlear implant insertion. The cochlear implant used will be either Med-El device with a Flex-28 electrode, Cochlea CO CI522 or advanced bionic HiFocus 1j.

A random number generator will be used to allocate each patient to an intervention group. This outcome will be stored in the patient notes, and also in a central trial database. The surgical intervention will be undertaken, and the details of the intervention will be stored in the patient notes, in keeping with routine clinical practice.

Included participants will undergo anaesthesia assessment, radiological imaging, and then randomised on an intention to treat basis between both surgical approaches of electrode insertion. The intervention will happen at the time of operation with an intention to perform one or other insertion technique based on the randomisation. Both surgical approaches are part of standard care. As part of lifelong follow up by the cochlear implant team, data from the first year will be acquired by the research team to determine outcome.

Intervention Type

Procedure/Surgery

Primary outcome measure
Pre-operative and post-operative unaided hearing threshold assessed at baseline, 1, 3, 6, and 12 months after the operation.

Secondary outcome measures
1. Post-operative physiological measures and fitting parameters by physiological (objective) outcome measures of the cochlear implant (electrode impedance, Evoked compound action potential (ECAP) maximum comfortable level (MCL), threshold level, eSRT). (1,3,6, and 12 months after the operation).
2. Post-operative speech perception measured by (Bench-Kowal-Bamford (BKB) sentence test in noise and in quiet, City University of New York Nonsense Syllable Test (CUNY) in noise and in quiet). (1,3,6 and 12 months after the operation).
3. Assessment of electrode position by cone beam CT scan (1 week after the operation).

Overall study start date
01/09/2017

Completion date
15/03/2023

Eligibility

Key inclusion criteria
1. >18 years old undergoing cochlear implantation.
2. Able and willing to give valid consent to the study.
3. Able to undergo pure tone audiometric testing as outlined.
4. Meet NICE criteria for cochlear implantation.
5. Working use of English.
6. Definable / measurable air conduction hearing threshold on pure tone audiometry at 250 Hz, 500 Hz and 1 kHz.
7. Patients choosing Med-El Flex28, cochlea Co.CI522 or Advanced bionic HiFocus 1j electrode array

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
54

Key exclusion criteria
1. Pre-operatively diagnosed cochlear obliteration.
2. Pre-operatively diagnosed inner ear dysplasia.
3. Undergoing bilateral implantation.
4. ‘Non-traditional’ cochlear implant candidates (pre-lingually deafened)
5. Contraindications to CT (e.g. pregnancy).
6. Contraindications to cochlear implantation (e.g. severe co-morbidity).
7. Contraindications to systemic steroid use (e.g. diabetes).
8. Previous middle ear surgery.
9. >90 years old.

Date of first enrolment
15/03/2019

Date of final enrolment
15/03/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal National Throat Nose and Ear Hospital (RNTNEH), University College Hospitals NHS Foundation Trust (UCLH)
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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
Med-El GmbH

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
15/06/2023

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

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?
HRA research summary			28/06/2023	No	No