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Human feasibility study of an implantable middle ear microphone

Submission date
19/04/2017

Recruitment status
No longer recruiting

Registration date
04/05/2017

Overall study status
Completed

Last Edited
14/06/2023

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
Hearing loss, or deafness, is a very common condition which develops as people get older. There are two main types of hearing loss: conductive hearing loss, where the problem is in the middle ear (i.e. in the ear drum) and sensorineural hearing loss (SNHL), where the problem lies in the inner ear (cochlea), or the nerve that carries information from the ear to the brain for interpretation. The cochlea is a complex part of the inner each which is responsible for converting sound waves into electrical messages which the brain can interpret. When the cochlea becomes damaged, standard hearing aids (which work by making sounds louder) do not work and so a cochlear implant is often recommended. Cochlear implants are electronic medical devices which are designed to do the work of the damaged cochlea. They have been used for some time in the treatment of those with severe or profound hearing loss. The use of these implantable devices has enabled those with severe hearing impairment to develop and participate in the day to day life of their families, education and workplace. The current design of the cochlear implant is less cumbersome than the early models, which included a body worn component, with a behind the ear component being the only visible part. However many ask why there needs to be any external components. Currently the microphone is part of the behind-the-ear sound processor. This project is looking at whether it is possible to develop a microphone that can be accurately placed in the most suitable position in the ear, to ensure that the instrument has the best possible outcomes for the patient in sound quality and in achieving a safer and more socially acceptable outcome. The aim of this study is to test the efficiency of a totally implantable microphone.

Who can participate?
Adults who have hearing difficulties and have used a cochlear implant for at least 12 months.

What does the study involve?
Participants who are taking part in the study undergo surgery to implant the microphone into one of their ears (the other ear that does not already have a cochlear implant). Three weeks after the surgery, participants are examined to make sure that everything is secure and healed properly. Once this is confirmed, the implanted microphone is switched on and the microphone in the Cochlear implant ear is switched off. For the next six months patients are monitored and the microphone is tested using hearing tests.

What are the possible benefits and risks of participating?
There will be no direct benefit for participants, but the results of the study are crucial to guide the development of a middle ear microphone. Participants are offered a free of charge standard cochlear implant and system at the end of the study. The implant might restrict activities participant are used to doing, such as swimming, diving or participating in contact sports. All these effects are temporary and will no longer be present when the device has been removed at the end of the study.

Where is the study run from?
Queen Elizabeth Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2015 to September 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Miss Amy Gosling
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Contact information

Type(s)
Public

Contact name
Miss Amy Gosling

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

33158

Study information

Scientific Title
SIME: Human Feasibility Study of an Implantable Middle Ear Microphone

Acronym
SIME

Study objectives
The aim of this study is to evaluate the clinical efficacy of a human grade middle ear microphone for cochlear implant users in terms of microphone sensitivity, noise floor, speech understanding, perception of body noise, and patient satisfaction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committees Northern Ireland, 09/02/2017, 17/NI/0012

Study design
Non-randomised; Interventional; Design type: Treatment, Device, Surgery

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Surgery, Primary sub-specialty: ENT Surgery; UKCRC code/ Disease: Ear/ Diseases of middle ear and mastoid

Interventions
Once participants have been given enough time to process the study and the information provided on the information sheet the Surgeon will consent the patient. After this the patient has a pre-operative assessment which occurs between 2-4 weeks before the surgery. Here they can ask any further queries for the surgery and the Health Utilities Index Questionnaire (HUI) is administered.

Two weeks before the surgery a patient will have a further pre-operative appointment to discuss the surgery in further detail and make sure all relevant information is collected. The patient will then have the surgery where a small incision will be made behind the ear. The surgery will involve implanting a middle ear microphone into the ear canal and will then be connected, via a thin cable to the Cochlear process that the patient will already have on their other ear (the point of the study is to test the efficiency of this Middle ear microphone).

Three weeks after the surgery the post-operative checks will occur, this is to make sure everything is secure and healed properly Once this is confirmed, the microphone is switched on and the microphone in the Cochlear implant ear is switched off.

For the next six months the patient will monitored and the microphone will be tested through audiology testing.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Implantable middle ear microphone

Primary outcome measure
1. Patient satisfaction is measured using the Health Utilities Index (HUI) is administered between 2-4 weeks operation, the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire and a study specific questionnaire that has been created for the SIME study along with the HUI 2 and 6 months after the operation
2. Microphone sensitivity will be measured by obtaining sound field thresholds in the sound field by using warble tones with the speaker positioned at 00azimuth relative to the subject's head. Measurements will be done at standard audiometric frequencies (250, 500, 750, 1000, 2000, 3000, 4000, 6000 Hz) using a standard audiometric technique (5 dB steps). This assessment will be carried out 4,8,12 and 16 weeks after the surgery.
3. Noise floor and speech understanding will be measured by English BKB sentences and AB words in the sound field using recorded speech and a standard audiometric technique with the speaker positioned at 00 azimuth relative to the subject's head. Word recognition scores will be measured at 45, 55 and 65 and 75 dB SPL, representing soft, conversational and loud presentation levels. This test is done with both quiet and noise in the sound fields. The speech intelligibility level in the presence of noise is used when assessing in a noise sound field. This assessment will be carried out 4,8,12 and 16 weeks after the surgery.
4. Perception of body noise are measured using bone conduction measurements using a bone conductor and a standard audiometric technique (5 dB steps) 4,8,12 and 16 weeks after the surgery

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/09/2015

Completion date

31/03/2019

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Fluent native speaker in language used to assess speech perception, i.e. English
3. Regular use of CI for minimum of 12 months
4. Speech performance criteria of at least 50% on BKB sentences in quiet with the CI at a presentation level of 70 dBA.
5. Willingness to have percutaneous plug and microphone implanted
6. Ability and willingness to perform audiometric tests and complete the study
7. Willingness to use the implanted microphone during the study outside the clinic in daily life environment.
8. Ability to provide useful feedback about the usage of the implanted microphone
9. Normal tympanometry.
10. No clinical, audiological or radiological evidence of abnormal ossicular chain

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 6; UK Sample Size: 6

Key exclusion criteria
1. Prelingually deafened adults
2. Active chronic otitis media
3. Participation in another medical device study
4. Unwillingness or inability of the subject to comply with all study requirements
5. Persons with mental, physical or geographic limitations that may render them incapable of completing scheduled study visits
6. Unrealistic expectations on the part of the subject regarding the possible benefits, risks and limitations inherent to the procedure and the device
7. Medical conditions that would contraindicate undergoing surgery or participation in the study
8. Any anticipated reason why removal of the implanted microphone could not be conducted after eight months of use.
9. Known risks to infection and healing
10. Known reason for requiring Magnetic Resonance Imaging (MRI) during the study

Date of first enrolment
24/02/2017

Date of final enrolment
01/07/2017

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
University Hospitals Birmingham NHS Foundation Trust

Sponsor details
Trust HQ
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type

Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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

Intention to publish date
31/05/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2022	14/06/2023	Yes	No
HRA research summary			26/07/2023	No	No