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Cochlear implantation in patients with single-sided deafness

Submission date
05/07/2013

Recruitment status
No longer recruiting

Registration date
05/07/2013

Overall study status
Completed

Last Edited
14/11/2018

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
Individuals with severe hearing loss in one ear only (referred to as single-side deafness or SSD) experience difficulty with understanding speech in background noise and with finding out where sounds are located. The standard of care for these people is a Contralateral Routing of Signals (CROS) system which picks up sound on the side of the deaf ear and delivers it to the opposite ear. A CROS system therefore improves the ability to hear sounds located on the side of the deaf ear but does not restore hearing to the deaf ear. Therefore, a CROS system does not improve the ability of people with SSD to separate information from multiple sounds positioned at different locations. A cochlear implant (CI) is a surgically fitted device which restores useful aspects of hearing to an otherwise deaf ear. In the UK, this is currently a recommended option for people with deafness in both ears. The aim of the study is to compare the benefits of using a CROS system to the benefits of cochlear implantation in people with SSD.

Who can participate?
The study will recruit adults with a substantial hearing loss (technically referred to as a 'severe-to-profound' loss) in one ear and normal hearing in the other ear. Eligible participants will be at least 18 years of age at the time of entering the study, have a good understanding of written and spoken English and have medical and physical fitness to undertake all of the study procedures which include undergoing general anaesthesia (sleep state) and surgery. Eligible participants must also not receive sufficient benefit from using a hearing aid in their deaf ear.

What does the study involve?
Participants will be assessed before receiving any treatment (baseline), after being fitted with a CROS system and after receiving a CI. Participants will complete a range of questionnaires: upon entering the study and after two months of no treatment, after one and three months of CROS use, and after three and nine months of CI use. The questionnaires will be completed at the participant's local cochlear implant centre. Participants will also travel to Nottingham to complete listening tests on three occasions: during the 2-month baseline period, after three months of CROS use, and after nine months of CI use.

What are the possible benefits and risks of participating?
Through the use of the CROS system or the CI, participants in the study may experience

improvements in their ability to perceive speech in the presence of background noise and to locate sounds. It is also possible that using either device may improve quality of life and may lead to a reduction in tinnitus (ringing in the ears) if present. There is some risk with either device that listening abilities may be reduced in certain specific listening situations. However, participants may choose to switch off either device, either at all times or in certain listening situations. There are no known risks associated with using a CROS system, nor with taking part in the study using this device. The risks associated with cochlear implantation include those normally associated with general anaesthesia. In addition, some nerves may be injured during surgery resulting in temporary or permanent facial weakness and/or a taste disturbance on one side of tongue. Following surgery, the wound site may become infected. There is a small increased risk of meningitis (infection of a protective covering around the brain) for which vaccination would be required before implantation to reduce this risk. There is a small risk that the CI may fail which would require additional surgery to correct. Patients with a CI must undergo special precautions before MRI (Magnetic Resonance Imaging) scanning or may be excluded from MRI scanning because the cochlear implant contains a small magnet.

Where is the study run from?
The study is being run by the NIHR Nottingham Hearing Biomedical Research Unit, Nottingham, UK. Participants will be recruited at five UK CI centres: the Nottingham Auditory Implant Programme (Nottingham), Midlands Hearing Implant Programme (Birmingham), Manchester Auditory Implant Centre (Manchester), St Thomas' Hospital Auditory Implant Service (London), and the Royal National Throat, Nose & Ear Hospital (London).

When is the study starting and how long is it expected to run for?
Recruitment begins in June 2013. The study is expected to run until the end of 2014.

Who is funding the study?
The study is funded by the National Institute for Health Research (NIHR) (UK), Nottingham University Hospitals NHS Trust (UK), the MRC Institute of Hearing Research (UK) and by industry support from Cochlear Europe Ltd.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14261

Study information

Scientific Title
Prospective within-subject comparison of the benefits of cochlear implantation versus contralateral routing of signal (CROS) hearing aids in adult patients with single-sided deafness

Study objectives
Relative to a contra-lateral routing of signals (CROS) hearing aid which is the current standard of care for single-sided deafness, cochlear implantation will improve the accuracy with which sounds can be localised and speech can be perceived in the presence of spatially-separated background noise. Relative to CROS, cochlear implantation may also reduce the degree of self-reported difficulty with listening and improve health-related quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
12/EM/0378; First MREC approval date 16/05/2013

Study design
Non-randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Ear; Subtopic: Ear (all Subtopics); Disease: Ear, nose & throat

Interventions
Contra-lateral routing of signals (CROS): All participants will undergo a 3-month trial of a CROS hearing aid. This device is the current standard of care for single-sided deafness.; Cochlear implantation (CI): Following the trial of the CROS hearing aid, participants may elect to undergo cochlear implantation. This device is the alternative intervention for single-sided deafness being evaluated.; Study Entry : Registration only.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Sound localisation; Timepoint(s): Before treatment (baseline), after 3 months of CROS use, after 9 months of CI use
2. Speech perception in noise; Timepoint(s): Before treatment (baseline), after 3 months of CROS use, after 9 months of CI use

Secondary outcome measures
1. EuroQoL; Timepoint(s): Before treatment (baseline), after 1 and 3 months of CROS use, after 3 and 9 months of CI use
2. Glasgow Benefits Inventory; Timepoint(s): After 1 and 3 months of CROS use, after 3 and 9 months of CI use
3. Glasgow Hearing Aid Benefit Profile; Timepoint(s): Before treatment (baseline), after 1 and 3 months of CROS use, after 3 and 9 months of CI use
4. Health Utilities Index Mark 3; Timepoint(s): Before treatment (baseline), after 1 and 3 months of CROS use, after 3 and 9 months of CI use
5. Speech Spatial Qualities; Timepoint(s): Before treatment (baseline), after 1 and 3 months of CROS use, after 3 and 9 months of CI use
7. Tinnitus Functional Index; Timepoint(s): Before treatment (baseline), after 1 and 3 months of CROS use, after 3 and 9 months of CI use

Overall study start date
29/05/2013

Completion date
01/04/2014

Eligibility

Key inclusion criteria
1. 18 years of age or older at the time of entry to the study
2. Able and willing to undertake all assessments required by the study
3. Good understanding of written and spoken English
4. Normal anatomy of the cochlea and auditory system on MRI scanning
5. Medical fitness to undergo general anaesthesia

6. Poorer ear (ear to be implanted):
6.1. Acquired (postl-ingual) severe to profound sensorineural hearing loss of greater than 6 months and <10 years duration. Severe to profound deafness defined as having hearing thresholds >90dB HL at 1 & 4 kHz, and no better than 65 dB HL at 500 Hz
6.2. Minimal benefit from hearing aids defined as scoring less than 50% on Bamford-Kowal-Bench (BKB) sentences presented at 70 dB SPL
7. Better ear (contralateral ear): Normal or near-normal hearing. For the purposes of this study this is defined as hearing thresholds with a pure-tone average (PTA) of = 30 dB HL at 500, 1000, and 2000 Hz
Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 10; UK Sample Size: 10

Key exclusion criteria
1. Evidence of middle-ear pathology based on otologic examination and immitance testing (NB: it is possible that some such cases might be resolvable by medical/surgical treatment, so that the subject may be eventually included)
2. Medical or psychological conditions that contraindicate undergoing surgery
3. Tinnitus as primary motivation for treatment
4. Abnormal anatomy of the cochlea that might prevent complete insertion of the electrode array and abnormalities of the auditory system
5. Hearing loss of neural or central origin, including auditory neuropathy and neurofibromatosis type II
6. Additional handicaps that would prevent or restrict participation in the audiological evaluations
7. Unrealistic expectations on the part of the subject regarding the possible benefits, risks, and limitations which are inherent to the surgical procedure and prosthetic device
8. Any known factor which would limit the benefit obtainable from a cochlear implant device

Date of first enrolment
01/06/2013

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
Midlands Hearing Implant Programme
Birmingham
United Kingdom
B15 2TH

Study participating centre
Manchester Auditory Implant Centre
Manchester
United Kingdom
M13 9PL

Study participating centre
St Thomas' Hospital Auditory Implant Service
London
United Kingdom
SE1 7EH

Study participating centre
The Royal National Throat, Nose & Ear Hospital
London
United Kingdom
WC1X 8DA

Sponsor information

Organisation

Nottingham University Hospitals NHS Trust (UK)

Sponsor details
MRC Institute of Hearing Research Nottingham Clinical Section
Eye Ear Nose and Throat Centre
Queens Medical Centre
Derby Road
Nottingham
England
United Kingdom
NG7 2UH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Research council

Funder Name
Cochlear Europe Limited (UK)

Funder Name
Nottingham Hearing Biomedical Research Unit (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/08/2014		Yes	No
HRA research summary			28/06/2023	No	No