ISRCTN72586805 https://doi.org/10.1186/ISRCTN72586805

Effects of treatment for vestibular schwannoma on hearing function

Submission date
03/01/2024

Recruitment status
No longer recruiting

Registration date
07/02/2024

Overall study status
Completed

Last Edited
04/03/2024

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims:
Vestibular schwannomas (VS) are non-cancerous tumours that grow on the hearing and balance nerve. These tumours can cause problems such as hearing loss, ringing or other noises in the head (tinnitus) and loss of balance. Treatment options for VS depend on tumour size and how fast it is growing. Small tumours are usually monitored using MRI scans (i.e., 'watch and wait'). Surgery may be needed to remove a large tumour or treat one that is growing. One type of treatment, stereotactic radiosurgery (SRS), uses a precise beam of radiation to arrest tumour growth. The 'watch and wait' treatment option presents a risk to hearing function as hearing often continues to deteriorate in the affected ear, even without obvious tumour growth. Some research studies suggest that stereotactic radiosurgery used at the time of tumour diagnosis, might delay hearing ability decline but the evidence is unclear. The aim of this study is to assess the viability of monitoring hearing function in people being managed for VS. The researchers want to understand which hearing function tests are best to evaluate the potential benefits of SRS compared with 'watch and wait'. They also aim to measure the reliability of the hearing tests over time.

Who can participate?:
Patients between 30 and 65 years of age who have a sporadic vestibular schwannoma and are either undergoing follow-up with serial MRI scans or are being considered for/have undergone treatment with SRS

What does the study involve?
At the testing session the researchers will carry out five hearing tests and complete two questionnaires.

What are the possible benefits and risks of participating?
Overall the results of this feasibility study will be used to help us better understand hearing loss in VS and answer an important question. Taking part in this study will not disadvantage participant's usual treatment in any way. All the hearing tests being used in this study are accepted clinical tools and there is minimal-to-no-excess risk to participants taking part in this study.

Where is the study run from?
Northern Care Alliance NHS Foundation Trust and the University of Manchester (UK)

When is the study starting and how long is it expected to run for?
October 2022 to February 2025

Who is funding the study?
NIHR Manchester Biomedical Research Centre (BRC) in Hearing Health (UK)

Who is the main contact?
Dr Daniel Lewis, daniel.lewis-3@manchester.ac.uk

Contact information

Type(s)
Principal investigator

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
321428

Protocol serial number
22NEURO19-S, IRAS 321428, CPMS 56401

Study information

Scientific Title
Effects of treatment for vestibular schwannoma on hearing function: a feasibility study

Study objectives
The primary aim of this pilot study is to determine the feasibility of using online hearing tests to monitor hearing function in participants with vestibular schwannoma (VS). Feasibility will be assessed via recruitment rates, completion rates and completion times for the full battery of hearing screening and hearing tests.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/07/2023, North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8290; gmeast.rec@hra.nhs.uk), ref: 23/NW/0149

Study design
Prospective single-centre non-randomized interventional study

Primary study design
Interventional

Study type(s)
Diagnostic, Quality of life, Screening

Health condition(s) or problem(s) studied
Vestibular schwannoma

Interventions
Participants will be asked to complete a number of hearing screening tests (otoscopy, tympanometry) and hearing-related outcome tests and questionnaires. The tests that will be included are as follows: otoscopy, tympanometry, pure-tone audiometry (PTA), Arthur Boothroyd (AB) word test, digits-in-noise (DIN) testing, Speech and Spatial Qualities of hearing scale (SSQ) questionnaire, and Tinnitus Functional Index (TFI) questionnaire. A subset of participants (n = 30) will be asked to repeat the DIN tests to measure the test-retest reliability of this outcome.

Intervention Type
Other

Primary outcome(s)
Speech recognition thresholds from a preliminary cross-sectional group (25 to 30 patients from each intervention) will be measured once at baseline using digits-in-noise (DIN) testing with the variance (standard deviation) in DIN speech recognition thresholds reported as the primary outcome measure

Key secondary outcome(s))
1. The clinical feasibility of measuring the effects of treatment (observation vs intervention with stereotactic radiosurgery [SRS]) for VS on hearing function, measured using:
1.1. Patient recruitment rates at 12 months into the study
1.2. Time to complete all hearing tests (pure tone audiometry, digits-in-noise [monaural and antiphasic], Speech, Spatial
and Qualities of hearing scale [SSQ], Tinnitus Functional Index [TFI])
1.3. Rates of completion of all hearing tests (pure tone audiometry, digits-in-noise [monaural and antiphasic], Speech, Spatial and Qualities of hearing scale [SSQ], Tinnitus Functional Index [TFI]), measured at the end of the study
2. Important factors that will inform a future RCT, specifically:
2.1. Patient attrition rates, measured at the end of the study
2.2. The total number of patients who do not meet the inclusion criteria throughout the course of the study
2.3. Outcomes: time taken per participant to collect all study data

Completion date
03/02/2025

Eligibility

Key inclusion criteria
1. Being diagnosed with sporadic vestibular schwannoma (VS) and tumour size <25 mm in the cerebellopontine angle (CPA)
2. Being ‘treated’ for VS with either radiological surveillance (‘watch and wait’) or SRS
3. Adults aged 30 – 65 years old
4. Adults with a mild-to-severe (pure-tone average across five audiometric frequencies between 20 and 70 dB HL) sensorineural hearing loss in at least one ear
5. Opinion of the treating clinician is that the patient will be able to successfully complete the research protocol
6. Normal otoscopy results
7. Normal middle ear health and function
8. Agreeing to have any excessive ear wax removed by a qualified audiologist
9. Native English speaker

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Have profound hearing loss
2. Tumours >25 mm in the CPA
3. Have type II neurofibromatosis (NF2)
4. Are currently taking ototoxic medication, such as aminoglycosides, carboplatin, cisplatin or any platinum-based cancer medications
5. Previous CNS radiotherapy/SRS

Date of first enrolment
19/10/2023

Date of final enrolment
03/01/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Northern Care Alliance NHS Foundation Trust
Salford Royal
Stott Lane
Salford
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M6 8HD

Study participating centre
Manchester Centre for Audiology and Deafness
School of Health Sciences, Faculty of Biology, Medicine and Health
Ellen Wilkinson Building, Oxford Road

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Sponsor information

Organisation
Northern Care Alliance NHS Foundation Trust

Funder(s)

Funder type
Research organisation

Funder Name
NIHR Manchester Biomedical Research Centre (BRC) in Hearing Health

Results and Publications

Individual participant data (IPD) sharing plan
Data used in the study will be available from the study coordinator (Dr Daniel Lewis, daniel.lewis-3@manchester.ac.uk) upon reasonable request with clear aims and respecting patient confidentiality. Individual patients will not be identifiable from any published data, tables or figures.

IPD sharing plan summary
Available on request