ISRCTN15178771 https://doi.org/10.1186/ISRCTN15178771

Efficacy of a combination hearing aid and sound generator

Submission date
16/04/2015

Recruitment status
No longer recruiting

Registration date
27/04/2015

Overall study status
Completed

Last Edited
12/02/2016

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
Tinnitus is a term used to describe a 'ringing in the ears' that comes from inside a person's body rather than from an outside source. There are various causes of tinnitus, and sometimes there is no identifiable cause. However, tinnitus is often triggered by hearing loss. Using a hearing aid can sometimes help people with tinnitus as it stops their ears straining to hear and helps with their hearing loss. There are also combination hearing aids which provide sound therapy, meaning they can make sounds in the environment louder to distract people from their tinnitus. Some of these combination hearing aids can produce natural sounds, such as rainfall or the ocean, to distract from tinnitus symptoms. In this study, a sound therapy hearing aid will be tested to see whether it works better at providing relief from tinnitus than a standard hearing aid in people with some degree of hearing loss.

Who can participate?
Adults with hearing loss and tinnitus.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) receive a sound therapy hearing aid alongside their usual care. Those in group 2 (control group) receive a standard hearing aid alongside their usual care. Participants use their devices for 6 months. Participants are asked to complete various questionnaires and have interviews with the clinician during the study. Follow up interviews take place 1 week after treatment, and again 1, 3 and 6 months later.

What are the possible benefits and risks of participating?
There are no specific risks associated with participating in this study.

Where is the study run from?
1. Cleveland Clinic (USA)
2. Cambridge University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2015 to October 2015

Who is funding the study?
Oticon A/S (Denmark)

Who is the main contact?
Dr D Baguley

Contact information

Type(s)
Public

Contact name
Dr David Baguley

Contact details
Hills Rd
Cambridge
United Kingdom
CB2 2QQ

Additional identifiers

EudraCT/CTIS number

IRAS number
167794

ClinicalTrials.gov number

Secondary identifying numbers
IRAS ID: 167794

Study information

Scientific Title
Efficacy of a combination hearing aid and sound generator: a randomised trial

Study objectives
The benefits of a device with combined hearing aid/sound generator functions are above that of a hearing aid alone, for adults with troublesome tinnitus. Furthermore, the device has good clinical efficacy and is easy for patients and clinicians to use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design

Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Tinnitus

Interventions
Participants are randomised to one of two groups.

Intervention group: participants will trial a hearing device with built-in tinnitus sound generator feature activated for six months at home, alongside standard care. Participants also receive guidance on use of the device.

Control group: participants will trial a conventional hearing device for six months at home, alongside standard care.

Intervention Type
Device

Primary outcome measure
1. Tinnitus Functional Index (TFI) to measure tinnitus severity
2. Tinnitus Acceptance Questionnaire (TAQ)

Secondary outcome measures
1. My Tinnitus document (self-report of symptoms)
2. Hearing Handicap Inventory (HHIA/HHIE) self-report measure of hearing-related disability
3. Patient interviews at each visit

Overall study start date
01/04/2015

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Hearing impaired with flat or mild to moderate-severe sloping sensorineural hearing loss (SNHL). Hearing loss can be asymmetrical provided participant has been medically cleared for red flag conditions by a physician or otolaryngologist.
2. No limitation on type of fitting that can be worn (e.g. open fitting, closed dome, ear mold allowed, depending on HL).
3. New hearing instrument users preferred to eliminate pre-user bias.
4. GAD-7 anxiety screening: score from 0-9, indicating no anxiety or minimal to mild anxiety only.
5. PHQ-9 depression screening: score from 0-9, indicating no depression or minimal to mild depression only.
6. TFI questionnaire: tinnitus symptoms ranging in severity rating from ≥32 to ≤71 points.
7. Age 18 and over
8. Only mild hyperacusis symptoms

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80. 40 in test group, 40 in control group. For each centre, 20 will be recruited from each group.

Key exclusion criteria
1. Clinical diagnosis of moderate to severe depression (score ≥10 in PHQ-9 screening)
2. Clinical diagnosis of moderate to severe anxiety disorder (score ≥10 in GAD-7 screening)
3. Patients with severe to profound hearing loss
4. Normal hearing tinnitus patients
5. Patients with very mild or severe to profound tinnitus symptoms
6. Patient where main symptom is hyperacusis
7. Patient cannot hear the sound generator signal at 82 dB(A)SPL

Date of first enrolment
01/04/2015

Date of final enrolment
01/07/2016

Locations

Countries of recruitment
England

United Kingdom

United States of America

Study participating centre
Cleveland Clinic
Head & Neck Institute
9500 Euclid Avenue, A71
Cleveland, Ohio
United States of America
44195

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Oticon A/S

Sponsor details
Kongebakken 9
Smoerum
Denmark
2765

Sponsor type
Industry

ROR
https://ror.org/05mwsq745

Funder(s)

Funder type
Industry

Funder Name

Oticon A/S (Denmark)

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