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Bone conduction devices in minimal air-bone gaps

Submission date
18/06/2025

Recruitment status
Recruiting

Registration date
23/06/2025

Overall study status
Ongoing

Last Edited
23/06/2025

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
Bone conduction devices (BCDs) are hearing aids which are given to people with a mixed or conductive hearing loss to improve their hearing. These devices deliver sounds to the patient by sending vibrations through the skull to stimulate the hearing organ. This study is looking to see if patients with a smaller degree of mixed or conductive hearing loss than would normally be considered for a BCD also benefit from a BCD when we compare their speech understanding with their conventional hearing aid.

Who can participate?
Adults (18 years of age and above) who are willing and able to provide written informed consent and are air conduction hearing aid (ACHA) users (including bilateral hearing aid users) with a recent fitting (<6 months)

What does the study involve?
Participants will be invited to two appointments at the hospital. At the first appointment an audiologist or a member from the research team will talk through the study and ask the participant to sign a consent form. A hearing test and some listening tests with the participant's current hearing aid(s) will be conducted. In addition, the participant will fill in some questionnaires about how they are feeling, and how well they are listening with their hearing aid (s). The local audiologist who is part of the research team will then fit a BCD on a softband for the participant to try out for 2 weeks. In about 2-6 weeks, the participant will come back to the hospital once for some more listening tests, this time with the BCD fitted in the previous appointment. A few more questionnaires on how listening with the BCD was and how it was different to their regular hearing aid(s) will also be filled out by the participant.

What are the possible benefits and risks of participating?
During the study period we do not anticipate any problems, but if any occur you can contact your local department for advice. The study hearing aid is fitted on a softband, which may or may not cause some discomfort when worn for a longer period of time.

Where is the study run from?
University College London Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2023 to March 2027

Who is funding the study?
Cochlear, who provide the study hearing aid, provide funding for the study but they are not in charge of any study operational matters and the study is fully sponsored by the University College London Hospital (UK)

Who is the main contact?
Mr Mark Chung, bcdabg.uclh@nhs.net

Contact information

Type(s)

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
332538

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 61324; Grant Code: IIR-2480

Study information

Scientific Title
Benefit from bone conduction devices in patients with minimal air-bone gaps

Study objectives
The primary study hypothesis is that patients with a small air-bone gap will have higher aided speech recognition in noise (measured using the Bamford-Kowal-Bench [BKB] test) when using bone conduction devices (BCDs) compared to conventional air conduction hearing aids (ACHAs).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/05/2024, South Central - Oxford A REC (Ground Floor Temple, Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 104 8118; oxforda.rec@hra.nhs.uk), ref: 24/SC/0140

Study design
Non-randomized; Interventional; Design type: Treatment, Device, Active Monitoring

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 to request a patient information sheet

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

Interventions
Patients will be identified by hearing aid centres or by a search through the hospital's audiology database.
Patients will be invited to participate via letter and sent a patient information sheet about the study, and asked to contact the clinic if they are interested in participating.
Patients will then be offered two appointments.

At the first appointment:
The patient will be consented to the study

If the patient consents to the study:
Their hearing will be checked to make sure it still fits the protocol
We will ask them about their hearing history and collect some basic demographic data (age in years, sex and ethnicity)
We will then test their speech understanding/listening with their hearing aids (ACHA)
We will take a reading from their hearing aids to see how much they wear them
We will ask them to fill in questionnaires:
1. The HUI3 to ask about quality of life factors
2. The SSQ12 to ask about how they hear with their ACHA
3. The HHIA to ask about their perceived difficulties in hearing with the ACHA
4. Part 1 of the GHADP

We will then fit them with a trial BCD on a softband for them to use for 4 weeks (+/-2 weeks).
We will ask them to wear it as much as possible until their next appointment.
The patient will then have a second appointment approximately 4 weeks later (+/- 2 weeks).

At the second appointment:
The patient will repeat the speech testing, but with the BCD this time.
We will take a reading from the BCD to see how much it was worn.
We will ask the participant to fill in the same questionnaires again, but relating to the BCD device they trialled. We will also ask them to fill in part 2 of the GHADP questionnaire to see if there are any differences between the two devices (ACHA vs BCD).
If the patient finds the trial successful, and they wish to discuss a BCD in more detail, they will be offered an appointment with an ENT consultant and move into the normal NHS BCD assessment pathway for the department.
Recruiting sites will send pseudanomymised data to UCLH for statistical analysis.
We do not expect any commercial intellectual property to be generated by this study; however, if these do arise, they will belong to UCLH as stated in the protocol.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Bone conduction devices

Primary outcome measure
Speech discrimination scores (assessed by BKB sentences and AB word lists) are compared between an acoustic hearing aid at baseline and with a bone conduction device after a 4-week (+/- 2 weeks) trial

Secondary outcome measures

Patient-reported outcome measures assessed by questionnaires at baseline and after 4 weeks (+/- 2 weeks trial):
1. Quality of life measured using Health Utilities Index (HUI-3)
2. Hearing disability in everyday situations assessed using Speech, Spatial, and Qualities of Hearing Scale 12-item version (SSQ-12)
3. Perceived hearing handicap assessed using the Hearing Handicap Inventory for Adults (HHIA)
4. Differences in perceived benefit between the two devices measured using the Glasgow HA difference profile (GHADP)

Overall study start date
18/04/2023

Completion date
01/03/2027

Eligibility

Key inclusion criteria
1. Adults (18 years of age and above)
2. Willing and able to provide written informed consent
3. ACHA user (including bilateral HA users) with recent fitting or HA adjustment (<6 months)
4. ABG between 15-30 dB (averaged over 0.5-2 kHz), with absolute unmasked BC thresholds <55 dBHL

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Inability to wear ACHA consistently
2. Inability to perform English speech tests and complete questionnaires independently
3. Rapidly changing or fluctuating hearing loss

Date of first enrolment
24/06/2024

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal National Ent and Eastman Dental Hospitals
47-49 Huntley Street
London
United Kingdom
WC1E 6DG

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Royal Hallamshire Hospital
Glossop Road
Sheffield
United Kingdom
S10 2JF

Study participating centre
University Hospital Birmingham
Queen Elizabeth Hospital
Edgbaston

Birmingham
United Kingdom
B15 2TH

Study participating centre
Basingstoke and North Hampshire Hospital
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
Lister Hospital
Coreys Mill Lane
Stevenage
United Kingdom
SG1 4AB

Sponsor information

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University College London Hospitals NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.uclh.nhs.uk/Pages/home.aspx

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Industry

Funder Name
Cochlear UK

Results and Publications

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

Intention to publish date

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

IPD sharing plan summary
Data sharing statement to be made available at a later date