Study Protocol and Statistical Analysis Plan

Hearing Aid Quality and Reliability Study

Version 1.0

05/12/2021

Version 2.0

03/01/2023

NCT04995666

Protocol Title

Hearing Aid Quality and Reliability Study

1 Background

Audeo Life is a new hearing aid designed to be waterproof. This additional waterproofing is the result of two key hardware changes: the internal components of Audeo PL coating and the charging posts have been replaced with an inductive charging system. Because there have been no changes to the function of the hearing aids themselves, there should be no difference in performance expected between the two technologies (Audeo Life and the existing Audeo P). However, we have no data on the physical durability and reliability of the Audeo Life outside of Laboratory Tests. The purpose of this study is to check the quality of the Phonak Audéo Life and the Charger Case Go to react to any critical issues prior to launch.

2 Objectives

The primary objective of this study is to confirm that for adults with mild to severe hearing loss, the Phonak Audéo Life functions as expected in terms of performance compared to baseline performance testing performed in Visit 1 as measured by electroacoustic evaluation using a test box measurement at user gain.

3 Description of the investigational device

The investigational device will be used according to its intended use to amplify and transmit to the ear and thereby compensate for impaired hearing. The fitting of the investigational device will be according to clinical practice by trained and qualified audiologists. This device is an additional product in the Paradise line. This is a new hearing aid designed to be waterproofThe device will be worn most waking hours in most daily activities, including showering, bathing, swimming, exercising and while perspiring.

4 Design of the clinical investigation

This clinical investigation is an interventional study, executed at one investigation site, with a confirmatory design. The investigation model is a single group and there is no masking (un-blinded).

5 Risks and benefits of the investigational device and clinical Investigation

There are minimal risks associated with both the investigational devices and participating in the clinical investigation. Identified risks are no greater than those associated with the daily use and wear of approved, available hearing aids.

6 Endpoints

The primary endpoint is an electroacoustic measurement of hearing aid function after a 90 day period of wearing the devices. The study may reveal that the product is robust and can

withstand adverse environments on human subjects. Conversely, it may reveal that the devices do not maintain their performance after being subjected to real-world, life situations. This may, in turn, delay development and/or launch of the intended product.

7 Inclusion and Exclusion Criteria

Inclusion criteria:

-N2, N3, or N4 sensorineural hearing loss
-Adult age 18 or older
-Participant must be willing to wear RIC devices in as many physically active environments as possible including showering and bathing

Exclusion criteria:

-Diagnosis that may cause fluctuations in hearing
-Unable to tolerate the physical fit of a RIC device coupled with standard silicone domes
-Inability to be seen for 3 lab visits

8 Measurements and procedures

Visit 1: (Day 1)20 participants will be invited to the study based on their hearing loss experience. Researcher will obtain an updated audiogram, if last audiogram obtained is older than 1 year. Participants will be fitted with a pair of investigational devices and a charger case. They will be instructed on use and care of the hearing aids and charger case. Participants will be instructed to use them in a variety of specific environments including while showering/bathing, exercising, while in pool, golfing, etc. Electroacoustic evaluation will be conducted on the hearing aids at Test settings and at User Gain settings for baseline information. Participants will be provided questionnaires for the home trial.

Visit 2: (Day 45) Participants will be asked if they have experienced any issues with hearing performance or sound quality (including feedback or gain changes) during the home trial. Participants will be asked to identify their charging behavior, including the number of charges from the onboard battery alone. Participants will be asked to provide any additional feedback regarding the hearing aids and charger case. Participants will be asked to rate the ease of use of the hearing aids and charger case. Participants will be asked to rate their comfort level wearing the hearing aids during the requested activities. They will be asked to rate their overall satisfaction with the hearing aids, charger case, and the combined system so far. If the participant requests any fine-tuning or adjustment to the hearing aid settings, they can do so at this time. . Electroacoustic evaluation will be conducted on the hearing aids at Test Settings and compared to the baseline testing.

Visit 3 (Day 90): Participants will come to the clinic to return the hearing aids and charger case. Datalogging information will be downloaded from the hearing aids to verify wearing times. Participants will be asked the same questions as on Visit 2. Electroacoustic evaluation will be conducted on the hearing aids at Test Settings and User Gain settings and compared to the baseline testing.

9 Statistical design and analysis plan

All subjects are exposed to the same treatment for the same total duration. As such, all subjects will be treated as a single cohort for analysis. The primary endpoint will be defined as a binary variable indicating whether the device performance has degraded as defined by comparing electroacoustic analysis (per ANSI S3.22-2014). Indicator of performance degradation in this investigation is: equivalent input noise (EIN) beyond the value specified on the product data sheet. All devices will be confirmed to comply with the data sheet prior to being dis-

pensed in the study. Devices which fail testing at the conclusion of the study will be recorded as a failure.

A device failure rate will be calculated as the percentage of all devices dispensed during the study which failed ANSI S3.22-2014 testing (on EIN) at the conclusion of the 90 day field trial. This value will be compared to the acceptance criterion of a 10% failure rate using a one sample binomial exact test. A p-value of less than 0.05 will indicate a statistically significant deviation in the sample from the acceptance criteria. **An observed failure rate significantly higher than 10% will indicate a failed acceptance criterion. An observed pass rate of 95% or higher will indicate a definitive pass acceptance criterion. In either of these cases, no statistical analysis will be necessary.**

Additional qualitative data will be collected regarding the participants' experiences, which will not be subjected to statistical analysis but will be summarized into key findings for the purpose of the study report.

10 Investigation Duration

The expected duration of each participant's participation is 90-100 days. The total expected duration of the clinical investigation is 15 weeks.

11 Data Handling and Management

Study data is recorded both with paper and with electronic Case Report Forms (p/eCRF). For each enrolled study participant a CRF is maintained. All CRFs are kept current to reflect the subject's status at each phase during the course of study. Participants cannot be identified in the CRF by name or initials and birth date but an appropriate coded identification is used. All study team members are authorized for the CRF entries and it is assured that any authorized person can be identified both for pCRFs and eCRFs. If pCRFs are used, the investigator's acronym as well as the subject ID is filled in and data are entered into an electronic file for analysis by the respective investigator and data get monitored by the assigned monitor. In case of a self-evident corrections, either the subject does it by himself or the investigator undertakes the correction by crossing out the word/sentence with a single horizontal line and by adding the correction including his personal identifier and the date.

Source documents for this investigation include, audiograms, Target fitting files, appointment checklists, and ANSI test measurement information and REM data.

All paper data will be stored in a locked filing cabinet at the Phonak Audiology Research Cen-ter (PARC). All electronic data files will be encrypted and stored on secure research computers. All identifying data will be stored at PARC.

The identifiable data kept at PARC will be destroyed as soon as the final analyses have been completed. The de-identified data will be kept for seven years after the publication of results. When the data are destroyed, paper records will be shredded by services provided at PARC. Electronic data will be encrypted as de-identified NOAH packages, where applicable, to be shared with Sonova Switzerland.

12 Amendments to the CIP

Amendments to the CIP, if necessary, will be updated with justification in this document.

The following amendments were added to version 2 of this document on 3/1/2023:

-In section 1.3, Measurements and Procedures, Visit 2: Added the step "electroacoustic evaluation will be conducted on the hearing aids at Test Settings settings and compared to

the baseline testing". This procedure, while not in the original CIP, was actually performed at the time of the study.

-Section 3.1, Preclinical Evidence and 3.2, Clinical Evidence to date:reference to the CER for Audeo P was added

-Section 5.3, Scientific Justification was added.

-Section 7.3.2 Primary analysis: Justification for not conducting a statistical analysis was added as the results revealed a 100% pass rate, and thus no statistical analysis was necessary.

13 Deviations from clinical investigation plan

Deviations from the CIP to protect the rights, safety and well-being of human participants under emergency circumstances may proceed without prior approval of the sponsor and the EC – such deviations will be documented and reported to the sponsor representative (Study Man-ager) and the EC as soon as possible. Apart from that the investigator is not allowed to deviate from this CIP unless that deviation does not influence the investigation data.

14 Device accountability

The PI or authorized designee keep records documenting the following in a written process:
• Names of participants who received, used, returned, or disposed of device

• Date of receipt, identification, and quantity of each investigational device (batch/serial number or unique code)

• Expirary date (if applicable)

• Dates of use

• Participant identification

15 Informed consent process

At the beginning of the first appointment, investigators will hand the consent form to the participant in a private setting and grant sufficient time to read the whole form. The consent form contains detailed information about incentives and reimbursement. Any questions will be answered and the participant will be given sufficient time to decide whether or not they want to participate in the study. After the participant signed two copies of the consent form, the researcher will sign both copies as well and provide one copy to the participant. In case of changes to the procedures described in the consent form, the participant will be informed at the beginning of an appointment.

Informed Consent will only be obtained by investigation participants who can provide informed consent themselves before enrollment.

16 Adverse events, adverse device effects and device deficiencies

Device deficiencies and all **adverse events (AE)** including all **serious adverse events (SAE)** are collected, fully investigated and documented in the source document and appropriate case report form (CRF) during the entire investigation period, i.e. from participant's informed con-sent until the last protocol-specific procedure, including a safety follow-up period (ISO_14155, 2020). Documentation includes dates of event, treatment,

resolution, assessment of serious-ness and causal relationship to device and/or investigation procedure.
Information on AEs is systematically collected during the regular investigation visits, and phone calls (if applicable).

The causality assessment of the SAE will be conducted according to MDCG 2020-10/1 Safety Reporting in Clinical Investigations of Medical Devices under Regulation (EU) 2017/745.

The reporting of Serious Adverse Events and Device Deficiencies follows the Regulation (EU) 2017/745 and the MDCG 2020-10/1 Safety Reporting in Clinical Investigations of Medical Devices under Regulation (EU) 2017/745.

17 Vulnerable Populations

The investigation does not include any vulnerable populations.

18 Suspension or premature termination of the clinical investigation

The clinical investigation will be suspended or prematurely terminated if the feature and/or investigative device malfunctions or if the participants or researchers are exposed to safety risks other than those outlined in this document. These events may include but are not limited to – natural disaster, widespread outbreak of illness, compromised structure of the investiga-tion site, etc. The trial will be suspended within 5 days of determination that the study or device puts subjects at an unreasonable risk (per 21 CFR 812).

There is a blinding code kept electronically with the study materials. This code can be used to link the participant with their study ID, if needed.

According to the FDA, follow-up is required for participants who experience serious adverse events. Follow-up will be conducted by the study manager until the nature of the event is resolved.

19 Publication policy

The clinical investigation will be registered in clinicaltrials.gov, a publicly accessible database, as required by US law.
The results of the clinical investigation will be documented internally in a study report.