

Study Protocol and Statistical Analysis Plan

Evaluation of a New Noise Reduction Strategy in Hearing Aids

Version 3

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NCT06138665

Protocol Title

1 Background

Several of Sonova's competitors have recently advertised that their devices use DNN for system steering. Sonova's new hearing aid uses real-time DNN denoising system. This exploratory study is intended to gather preliminary data about the benefits of the newest noise reduction feature using DNN, compared to competitive devices in the domains of speech intelligibility with competing talkers, listening effort, and subjective preference.

2 Objectives

The primary objective of this study is to examine the speech intelligibility performance in noise for experienced hearing aid users with moderate to severe hearing loss when competing talkers are present, compared to the performance with the current noise reduction feature available in competitive devices via the Coordinate Response Measure task.

A secondary objective is to measure listening effort for experienced hearing aid users with moderate to severe hearing loss, with the DNN feature and compare to the performance of competitive devices via the Adaptive Categorical Listening Effort Scale (ACALES) task developed by the University of Oldenburg.

A tertiary objective is to obtain subjective evaluation of all three device on various sound characteristics: noise suppression, speech clarity, speech loudness, speech naturalness, speech and noise separation, and overall satisfaction.

3 Description of the investigational device

The investigational device is a receiver in the canal (RIC) hearing aid which is intended to amplify and transmit sound to the ear and thereby compensate for impaired hearing.

4 Design of the clinical investigation

This clinical investigation is an interventional study executed at one investigation site with an exploratory design. The investigation model is a single group and is single-blinded. There is a cross-over aspect in that participants will complete the same study tasks with three different devices.

5 Risks and benefits of the investigational device and clinical investigation

There are minimal risks associated with both the investigational device 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. The device used presents non-significant risk per FDA.

The benefits of participating in the investigation include the possibility of hearing sounds that have not been previously heard, such as speech and environmental sounds, which may improve communication in daily life. Subjects may experience the benefit of personal satisfaction for participating in research to improve hearing instrument technology. Subjects will also be compensated for their time in participating in this study.

There are no known or anticipated risks to subject hearing ability associated with participation in this study. All sounds used in this study will be presented at safe listening levels. While using hearing aids, the following are possible occurrences:

- Cerumen impaction
- Ear discomfort, pain or soreness
- Sweat or moisture accumulation in the ear canal or pinna
- A feeling of pressure or fullness in the ear

- Itching, blisters, or sores in the ear canal or pinna
- Headache
- Redness of tissue

The research personnel will review these risks with the subjects and answer any questions they have. Hearing aids are not a significant risk investigational device as defined in the FDA 21 CFR 812.3(m).

6 Endpoints

Primary endpoint:

- Accuracy on the CRM task: this endpoint will be used to measure speech intelligibility in noise.

Secondary endpoint:

- Categorical rating of listening effort via the ACALES: this endpoint will be used to measure the amount of listening effort a participant subjectively experienced.
- Subjective ratings of noise suppression, speech clarity, speech loudness, speech naturalness, speech and noise separation, and overall satisfaction using a Likert scale from 1 (poorest) to 5 (best).

7 Inclusion and Exclusion Criteria

Subjects fulfilling all of the following inclusion criteria are eligible for the investigation:

- 18-90 years old
- Bilateral sensorineural hearing loss, any degree
- Good written and spoken English language skills
- Experienced hearing aid user
- Able to produce a reliable hearing test result
- Willing and able to provide informed consent

The presence of any one of the following exclusion criteria will lead to the exclusion of the subject:

- Has auricle deformities, that prevents secure placement of the hearing aids
- Self-reported ear-related pathology (otorrhea w/in 90 days, dizziness, sudden hearing loss or worsening of hearing w/in 90 days, otalgia)
- Chronic, severe tinnitus
- Cognitive impairment
- Unilateral hearing loss

8 Measurements and procedures

The following procedures will be included in this investigation:

Cerumen management may be necessary prior to fitting hearing aid

Audiogram

Hearing aid fitting

Coordinate Response Measure

Listening Effort

Subjective ratings using a Likert scale

9 Statistical design and analysis

A priori sample size estimation was not performed for this investigation, as the investigation is exploratory and does not aim to confirm any effect with statistical significance and power.

However, statistical analysis will take place upon the conclusion of data collection. Summary statistics will be run as well as exploratory analyses.

Data from the CRM task will be analyzed to explore the effects of the noise reduction feature, target location and target voice.

Data from the LE task will be analyzed to explore the effects of the noise reduction feature.

Data from the subjective ratings will be used to report subjective preferences and overall ranking of the three devices-no statistical analysis will be completed for this outcome measure.

10 Investigation Duration

Expected duration for each participant is approximately 2 hours for one day. The entire investigation is expected to take approximately 2-3 weeks.

11 Data handling and management

Electronic or paper based CRFs will be used to capture the participant data. If electronic, subjective questionnaires will be available in the EDC system and the participant will be able to read question and choose answer. If paper based subjective questionnaires are used, the participant will answer each question and the results will be transferred to the EDC by the investigator. Objective data will either be entered directly to the EDC system, or transferred from a paper based CRF into the EDC system.

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 initials and subject ID are documented and data are entered into an electronic file for analysis by the respective investigator and data will be 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.

The results for the audiometer-based objective measure will be taken from the computer used to complete the test and imported into the EDC system or transferred via an excel or csv file. Real Ear Measurements will be imported from the verification system and stored as an excel file.

The pCRFs/eCRFs are only available to the local study team and to the monitor of the study.

In the case of an audit or a serious adverse event, the CRFs may need to be de-anonymized and sent to the governing body (i.e FDA) or insurance company.

Any paper-based data will be stored in a locked filing cabinet at the investigation site. All electronic data will be stored on an access-restricted server owned, operated, and maintained by Sonova USA. Servers used to store data in this investigation are physically located in the US. Permission to access data will be limited to study manager, monitor, PI, and essential research staff, as designated by the principal investigator.

During data collection of the investigation, physical copies of the data will be compiled and digitized by the study manager/investigator on a daily basis. Data will be reviewed for mis-entries or inaccuracies as each data set is entered.

The extent and nature of monitoring appropriate for the clinical investigation including the strategy for source data verification (SDV) are based on considerations such as the objective, design, complexity, size critical data points and endpoints of the clinical investigation. A de-tailed plan for monitoring arrangements is provided separately from this CIP.

12 Amendments to the CIP

Any necessary amendments to the CIP will be communicated to the study manager/sponsor.

A new version of the CIP will be written, with the necessary changes and justification, and the PI will be trained on the amendments. The amended CIP will go through the approval process and necessary signatures obtained from the study manager/sponsor, PI, and statistician. The amended CIP will be uploaded to the eQMS system as an additional revision.

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 Manager) 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

Sonova, in its capacity as sponsor, will maintain a log of all investigational devices, including the date of shipment from Sonova to the site, serial number, receiving study site, and date returned to Sonova.

The site will maintain a log of the devices provided by Sonova, including the date of receipt, serial number, date of fitting, participant identification, date of return to site by participant, and date returned to Sonova. Sonova will provide each site a template with which to record such information.

If a device needs to be replaced due to a device deficiency, the PI or sub-investigator will add the new device serial number, date of receipt, and date of return of the defective device on the Device Accountability Log.

In the case of a device deficiency, the Adverse Event-Device Deficiency form will be completed by the study manager and the PI or sub-investigators together.

15 Informed consent process

Informed consent will be obtained from participants prior to any study participation in accordance with the IRB guidelines. The participants will be granted sufficient time to read through the consent in full and ask any questions they have before signing. After the participant signs the consent form, the researcher will sign and provide a copy to the participant. This process will take place in a private office located in the Phonak Audiology Research Center (PARC).

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 consent until the last protocol-specific procedure, including a safety follow-up period (ISO-14155, 2020). Documentation includes dates of event, treatment, resolution, assessment of seriousness 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 investigator(s) will follow-up on a biweekly basis with any participant experiencing an AE until either a) the participant reports resolution of the AE or b) 8 weeks have passed since the participant's final visit. If, however, the participant's condition worsens throughout the 8 week follow-up period, the investigator will continue to follow-up biweekly until the AE is resolved or the participant's condition stabilizes over an 8 week period.

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. 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.

17 Vulnerable populations

This investigation will not include any vulnerable populations.

18 Suspension or premature termination of the clinical investigation

The study will be terminated if the majority of the participants are not able to wear the devices for the study visit. The study will be terminated if the participants or researchers are exposed to safety risks other than those outlined in this document.

The study may be terminated in the event natural disasters, widespread outbreak of illness, compromised structure of the investigation site, etc. that would make continuation of the study impossible or impractical. The study will be suspended within 5 days of determination that the study or device put participants at an unreasonable risk.

If a participant is suspended, terminated, or withdraws from the study, their data can be traced with their unique study identification number.

According to the FDA, follow-up is required for participants who experience Serious Adverse Events. Follow up will be conducted by the study manager and/or the PI 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 U.S. regulations.

The results of the clinical investigation will be published on clinicaltrials.gov no later than one calendar year following the final participant appointment.

An internal report of the results of this investigation will be completed and uploaded to eQMS.