Study Protocol and Statistical Analysis Plan

Evaluation of New Fitting Characteristics for Extended Wear Hearing Aid Technology

Version 1.0

March 16, 2022

NCT05274165

Protocol Title

See cover page of original CIP

1 Background

Since its original launch in 2008, the Lyric device has offered hearing impaired patients an invisible and more convenient option when compared to conventional daily wear hearing aids. Designed to be worn in the ear canal for several weeks or months at a time, this extended wear, non-custom hearing aid has gone through several iterations and product improvements in the last decade. These product improvements included an expanded size offering in 2017. However, even with this expanded size offering, discomfort, migration, feedback and sound quality continue to be reasons for trial cancellations. These issues are often caused by a less than ideal fit, especially if a patient has a conical shaped, or narrowing, ear canal. This study aims to evaluate the Trial-to-Success Rate for devices that have modified seals with additional sizes, compared to the conventional or current offering of seal sizes.

2 Objectives

The primary objective is to determine if the availability of additional Lyric sizes results in a higher TSR for new Lyric patients as compared to new patients who are offered only traditional sizes.
Safety objective is to track and document any adverse events related to the investigational device and the study procedure.

3 Description of the investigational device

The Lyric4 device is an analog hearing instrument that is deeply inserted in the ear canal. It consists of an electronic module and two seals, a medial and lateral, glued onto the electronic module.
The overall intended purpose of the device is to amplify and transmit sound at the ear and thereby compensate for impaired hearing. The investigational device is made of the same components as the commercially available Lyric4 device, but allows for different seal sizes. This may improve the comfort and lead to increased fittings and subscriptions.

4 Design of the clinical investigation

This exploratory study will have two conditions (Lyric4 only and Lyric4+Modified Seals) across a sample of 40 human subjects, 20 in each group. The participant placement will be counter- balanced to ensure a variety of ear canal sizes and shapes in both groups, and the participants will be blinded to the 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

To satisfy the primary objective, a subjective questionnaire will be administered to each participant after the 30 day trial period, before devices are removed. Question domains will focus on intent to purchase, but may also include topics on comfort and sound quality.

7 Inclusion and Exclusion Criteria

Inclusion criteria:
-Mild to moderate bilateral hearing loss
-Ear canal length minimum of 4 mm
-Ear canal geometry such that a Lyric device can fit comfortably and is deemed an appropriate fit by the clinician
-Meets all other candidacy requirements listed on the Lyric Candidacy form (exclusions below)
-18+ years
-Willing to trial devices for 30 days with the knowledge they may not be able to purchase
Exclusion criteria:
-History of radiation therapy to the head or neck
-Middle ear conditions such as TM performation, PE tubes, or cholesteotoma
-Requires regular MRI testing which would occur during study period
-Unable or unwilling to tolerate the physical fit of a Lyric devie
-Inability or unwilling to be seen for 3-4 lab visits

8 Measurements and procedures

Patients who meet the Lyric candidacy criteria will be put into one of two groups. The control group will be offered only the currently available sizes of Lyric, which is representative of the current commercial offering for Lyric. The experimental group will be offered all current sizes as well as the additional sizes. Participants will be fit with the most appropriate size available to them in their group. Participants can be re-fit with a different size within that group if the initial device is not the best fit. After a 30 day trial period, participants will be given specific cost details and asked about their intent to purchase, before being told which device they were wearing. Simulated TSR for each group will be calculated based on the participants' intent to purchase.
All analysis of the results will occur at the conclusion of the study. All study data will be stored digitally. The data will be collected from the participants using paper questionnaires or an online survey tool (i.e. Alchemer) and then stored in an excel file for analysis. Collection of the questionnaire results will occur

on an ongoing basis. The lead investigator will scan any paper questionnaires and send them to the study monitor via email. All original copies of the questionnaires will be stored at the investigation site.

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. Due to the exploratory nature of this investigation, an informal exploration of the data will be performed at the conclusion of the trial. No further statistical analysis is planned.

10 Investigation Duration

The investigation is expected to have a total duration of 6-8 months. The expected duration for each participant is approximately 30 days.

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 in 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 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.
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 sub-investigator's clinic.

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 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 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.