Study Protocol and Statistical Analysis Plan

Evaluation of Extended Wear Technology

V 2.0

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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 still account for a large number of trial cancellations. These issues are often caused by a less than ideal fit, especially if a patient has narrowing ear canal.

2 Objectives

The primary objective is to determine if patients who have rejected or cancelled Lyric subscriptions within the last two years due to discomfort or feedback, migration or poor sound quality (due to poor fit) rate the investigational Lyric4 devices with a fitting modification as more comfortable than the conventional Lyric4 devices.

There are no secondary objectives.

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. Currently, the Lyric4 is available in seven non-custom sizes: XXS, XS, S, M, L, XL, and XXL. The investigational device is made of the same components of the commercially available Lyric4 device, but with a fitting modification which may allow for an improved fit for narrower ear canals and increase the size options.

4 Design of the clinical investigation

This will be an interventional, single group design with two conditions (Lyric4 and Lyric4 with fitting modification) where subjects will wear the currently available Lyric device in one ear and the investigational device in the opposite ear for two weeks; and then switch ears for two additional weeks. Subjects will be blinded as to which device is in each ear.

5 Risks and benefits of the investigational device and clinical Investigation

The product-related risks and the clinical investigation procedure-related risks are well-controlled during the clinical investigation as the subject is under the care of a well-established, Lyric-trained, hearing health care provider. Any ear health risk from this investigation is no greater than any risk a hearing impaired patient experiences when undergoing a Lyric trial with a certified Lyric provider.

The study may reveal that the investigational devices are more comfortable for those patients who were unable to wear Lyric devices previously, thus implying an improved fit rate. The investigational devices are not custom, and do not require extensive modifications of the Lyric component itself. If improved fit rate can be confirmed, it is

likely that more hearing impaired patients who would like to experience the benefits of an extended wear device would be able to do so.

6 Endpoints

To satisfy the primary objective, subjective questionnaires will be administered after each device fitting and removal. Question domains may include, but are not limited to, comfort, occlusion, feedback, sound quality, and purchasing interest.

7 Inclusion and Exclusion Criteria

Inclusion criteria: Hearing loss N2-N4 (mild to moderate)

Hearing impairment: Any (conductive or sensorineural)

Population: Adults

Minimum Age: 18 years

Maximum Age: 90 years

Other: Previous Lyric users who rejected or cancelled Lyric trials or subscriptions due to discomfort, feedback, migration, or poor sound quality due to fit issues.

Exclusion criteria: Participants who can only wear a size XXS Lyric will be excluded as even an XXS investigational device would likely not be any more beneficial than a conventional XXS Lyric4 device.

Asymmetrical hearing loss

Other diagnosis that may cause fluctuations in hearing (i.e. Meniere's disease)

Unable to tolerate the physical fit of a Lyric device

Inability to be seen for 4 lab visits

8 Measurements and procedures

Investigation related procedures:

Study Procedure	**Impact on subject**	**Standard of care?**
Audiogram; may be done if most recent audiogram is more than 12 months old	Assesses hearing loss	Yes
Cerumen management	Clears ear canal of wax	Yes
Ear mold impression; may be done for future analysis of ear shape	Takes custom impression of ear	Yes

Fit with Lyric devices	Provides prescriptive amplification	Yes
Questionnaires; will be completed after each home trial for both devices	Assesses subjective relating to the investigational device/feature	No –These questionnaires were designed for this specific study. They are not validated for clinical outcomes.

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 and then be stored in an excel file for analysis. Collection of the questionnaire results will occur on an ongoing basis. The lead investigator will scan the paper questionnaires and send them to the study manager via email. All original copies of the questionnaires will be stored at the investigation site until the conclusion of the study, at which point they will be mailed to the study manager. Only authorized research personnel at the sponsor site will have access to the study results.

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.

This is an exploratory trial and will not have statistical criteria for termination.

The experiment performed within this study is designed to evaluate the efficacy and effectiveness of new fitting characteristics to the Lyric extended-wear hearing technology as compared to the commercially available Lyric device. The statistical hypothesis is that average ratings of wearing comfort with the new technology will be equivalent to or better than the commercially available technology. A qualitative analysis of the questionnaires will be used for data analysis. Qualitative data will be collected as a question, response, and anonymous participant ID for all participants at each device fitting and removal.

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.

All safety related events will be constantly monitored by the investigators and will immediately reported to the Principle Investigator. Evaluation of any SAE, SADE, or UADE will be conducted promptly using Sonova's standard medical device referral protocol. Confirmed UADEs will be reported to the IRB within 10 days after receiving notice of the event. If it is determined that an event or effect presents an unreasonable risk to subjects, this study, or those parts of the study presenting that risk, will be terminated no later than 5 working days after the determination is made and no later than 15 working days after Sonova USA first received notice of the event.

A safety analysis of the relevant data will be done after the data collection is finished.

Deviations to the statistical plan will be captured and reported in an update to this document, with justification.

If data records are complete from subjects who dropped out of the study early, these data will also be used in the analysis. If the data sets are not complete, they will not be integrated at all. If a subject is dropping out before data collection is finished, the study team will try to complete as many data sets as possible. If a subject drops out before the first study visit the subject will be replaced if possible.

10 Investigation Duration

The investigation is expected to last approximately 8 weeks. The expected duration for participation by the subjects is 4-5 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, ALPs fitting files, Lyric history, including prior adverse events, appointment checklists, and paper copies of the subjective questionnaires.

All paper data will be stored in a locked filing cabinet at the Phonak Audiology Research Center (PARC). All electronic data files will be encrypted and stored on secure research computers. All identifying data will be stored at the site. De-identified data will be shared, if necessary, with production to cross-check the quality of scans/impressions, and with partners at Sonova Switzerland.

The identifiable data 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 study plan, if necessary, will be updated with justification in this document.

13 Deviations from clinical investigation plan

Deviations from the study plan 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 study plan unless that deviation does not influence the investigation data.

14 Device accountability

The sub-investigator at site or authorized designee will 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)
- Expiry date (if applicable)
- Date(s) of use
- Participant identification

15 Informed consent process

At the beginning of the first appointment, the investigator 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 consent until the last protocol-specific procedure, including a safety follow-up period (ISO_14155, 2020)

Evaluation of any SAE, SADE, or UADE will be conducted promptly using Sonova's standard medical device referral protocol.

In the event of an adverse event, the investigation manager will make contact with the principal investigator within 24 hours to align on reporting procedures and to evaluate the relationship of the investigational device and the related procedure.

In the event of a serious adverse event, this will be reported to the FDA using Reporting Form FDA 3500, or by telephone at 1-800-FDA-1088.

Confirmed UADEs will be reported to the IRB within 10 days after receiving notice of the event. If it is determined that an event or effect presents an unreasonable risk to subjects, this study, or those parts of the study presenting that risk, will be terminated no later than 5 working days after the determination is made and no later than 15 working days after Sonova USA first received notice of the event.

A causal relationship towards the medical device or investigation procedure should be rated as follows:

Not related: The relationship to the device or procedures can be excluded.

Unlikely: The relationship with the use of the device seems not relevant and/or the event can be reasonably explained by another cause, but additional information may be obtained.

Possible: The relationship with the use of the investigational device is weak but cannot be ruled out completely. Alternative causes are also possible.

Probable: The relationship with the use of the investigational device seems relevant and/or the event cannot be reasonably explained by another cause.

Causal relationship: The serious event is associated with the investigational device or with procedures beyond reasonable doubt.

Device deficiencies that might have led to an SAE are always related to the medical device.

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 investigation site, etc.

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 with the possibility of an online publication.