Study Protocol and Statistical Analysis Plan

Active vent Performance Study – ID# 366

May 11, 2022

NCT04774185

Active vent Performance Study – ID SRF-366

1 Objectives and hypotheses of the clinical investigation

1.1 Purpose of the clinical investigation claims for clinical performance, effectiveness or safety of the investigational device that are to be verified

(P) The patient poblem is own-voice amplificaiton with closed vents. (I) A conventaional solution are open dome fittings. However the side effect is reduced low frequency sound procesing in hearing aids, and thus reduce sound processor benefit. Sonova has introduced an active vent feature based on a new RIC with an internal actuattor that controls a physical venting mechanism. (C) Thus the investigation will focus on the comparison between hearing aids fitted with the new active vent over an open dome. (O) The active vent is expected to provide

a. Improved speech intelligibility when listening to speech in noise using beam-forming in a closed-vent condition,
a. Improved sound quality of streaming music and speech when in a closed-vent condition, and
b. Comparable own-voice comfort in an open-dome condition.

1.2 Primary and Secondary Objectives

Primary Objective:

Evaluate whether Phonak Audéo P90-R in combination with an ActiveVent (AV) receiver provides better speech intelligibility for speech in noise than Phonak AudéoP90-R with a standard receiver and an appropriate* standard dome AND providing natural sound in everyday listen-ing situations for people with mild to moderate hearing loss.

Secondary Objective(s):

Evaluate whether Phonak Audéo P90-R in combination with an ActiveVent (AV) receiver improves listening effort compared to Phonak AudéoP90-R with a standard receiver and an appropriate* standard dome in everyday listening (communication) situations for people with mild to moderate hearing loss.

Evaluate whether Phonak Audéo P90-R in combination with an ActiveVent (AV) receiver provides same own voice perception than Phonak Audéo P90-R with a standard receiver and an appropriate* standard dome for people with mild to moderate hearing loss.

Evaluate whether Phonak Audéo P90-R in combination with an ActiveVent (AV) receiver improves sound quality compared to Phonak AudéoP90-R with a standard receiver and an appropriate* standard dome when listening to streamed music and speech for people with mild to moderate hearing loss.

2 Design of the clinical investigation

2.1 General

2.1.1 Design Type

The study will be a single-blinded randomize cross-over design. The comparison of devices will be done within participant, whereby each participant will be asked to perform a behavioral assessment using both fitting modalities, active vent and open dome.

2.1.2 Procedures

2.1.3 Investigation-related Procedure

Participants will not be treated for hearing loss. A standard PTA will be administered during the appointment for the purpose of candidature screening and fitting the hearing aids for testing. The hearing aids will be fitted to match NAL-NL2 targets, using standard audiometric procedures.

3 Statistical design and analysis

3.1 Determination of Sample Size

Power analysis using published data [Keiser et al., International Journal of Audiology Volume 52, 2013 - Issue 11] suggest that to reached sensitive of 1 dB shift in intelligibility thresholds between RIC closed to open states, the study requires N = 21 (Z-statistics), at at $\delta = 1.41$ dB, $\alpha = 0.05$, $\beta = 0.1$.

Due to the low sensitivity of the intelligibility test we planned to include 26 participants

3.2 Statistical criteria of termination of trial

Describe the criteria for the termination of the trial or the stopping rules. Trial will be terminated if the participant is not able to

1. If this not possible to reach convergence in the adaptive intelligibility test, which requires a standard error of 0.8 dB SNR.

3.3 Planned Analyses

The statistical analysis plan includes the methods and types of the analysis, the variables the data sets and the timeframe when the (interim) analysis is planned.

3.3.1 Datasets to be analyzed, analysis population

n/a

3.3.2 Primary Analysis

A linear mixed effect model will be used to analyze the intelligibility and sound quality benefits. The fixed effects in this model will be fitting modalities (AV: closed, AV vent open, Open dome), average hearing loss (in dB HL), and order of feature tested (first or second). The random effect will be a subject-specific intercepts. This analysis will be conducted by the PI.

3.3.3 Secondary Analysis

ANOVA for own voice investigation.

This analysis will be conducted by the PI.

Amendment will be done if the protocol of the home trial is developed.

3.3.4 Interim Analysis
Analysis is done on regular basis for updating the sponsor on the available data set.

=> no final conclusions!

3.3.5 Safety Analysis
Describe the analysis of the safety parameters that will be done, when and how and by whom it will be done.

In case of reported AEs those will be reported to the ethic committee and the study manager within 24h.

3.3.6 Deviation(s) from the original statistical plan
Any additions or changes of the statistical analysis will be reported in the study report with proper justification.

3.3.7 Handling of missing data and drop-outs
In case of missing data those will be ignored but the remaining data set will be considered in data analysis especially because of the small sample size.

4 Informed consent process

4.1 Process for obtaining informed consent

NAL processing requires participants to be identified from the NAL database or from the Hearing Australia database. All participants listed in the NAL database are volunteers willing to participate in re-search. All participants from hearing Australia are clients of Hearing Australia who have not opted out of research with NAL during their registration to received clinical services.

Regardless of the database source, participants are first contacted by phone, mail or email, depending on their preferred contact methods. An invitation letter is sent to them which describes the task involved and the overall aim of the study. The invitation letter template is attached to the ethics documentation. Their participation is voluntary, but they are told of the payment they will be received upon participation. The payment is calculated based on the effort of the task required by the study, distance of travel requirements to attend the clinic, and urgency of recruitment, e.g., high pay is provided for longer lengths of travel and longer appointments.

Upon responding to mail or email invite letter, participants are contacted, with the preferred method being a phone call unless participants prefer an alternative approach. During this call, participants are given a more detailed description of the task required by the study, appointments times available, and payment methods. At this point, if participants wish to proceed, a time is scheduled to start the appoint-ment.

Upon participant arrival, the first task is to sign off the consent form, as per the ethics application. Before signing the consent form, participants are asked if they have any questions or concerns about the study.

Information is provided as best understood by the clinician at the time.

Suppose that at any time during the appointment the task divergences from protocol and this impacts on timing or data collected. In that case, an explanation is provided to the participant if they are willing to remain for an extra period or stop at the agreed time, with no penalty to payment. Depending on the extension of the additional work, additional payment may be offered.