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# Statistical Analysis Plan

# A clinical investigation comparing a standard hearing aid fitting protocol and a fitting protocol optimized for musicians

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|---|---|
| Study Type: | Clinical trial with Investigational Medical Device (MD) |
| Study Categorisation: | Category A; MD with CE mark |
| Study Registration: | SNCTP, EudraCT |
| Study Identifier: | BF006-1902 |
| Sponsor, Sponsor | Bernafon AG<br>Morgenstrasse 131, 3018 Bern |
| Investigational Product: | Hearing Instrument; Viron 9 MNR |
| Protocol Version and Date: | Version 1.0, Final Document |

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# 1. ADMINISTRATIVE INFORMATION

## 1.1 Title and trial registration

| | |
|---|---|
| Study number | SNCTP; EudraCT, registration number (TBD) |
| Study Title | A clinical investigation comparing a standard hearing aid fitting protocol and a fitting protocol optimized for musicians |

## 1.2 SAP and protocol version

| Date | SAP Version | CIP Version | Identification | Comment |
|---|---|---|---|---|
| 2019.07.22 | 1.0 | 1.0 | Christophe Lesimple | Document created |
| | | | | |

## 1.3 Roles and Responsibilities

**Sponsor, Sponsor-Investigator**

Bernafon AG, Morgenstrasse 131, 3018 Bern, Tel. +41 31 998 01 01

**Principal Investigator(s)**

Barbara Simon, Research Audiologist, Morgenstrasse 131, 3018 Bern, Tel. +41 31 998 16 46, Email: bsim@bernafon.com

**Statistician ("Biostatistician")**

Christophe Lesimple, Clinical Research Audiologist, Morgenstrasse 131, 3018 Bern, Tel. +41 31 998 17 03, Email: cles@bernafon.com

**Monitoring institution**

Bernafon uses monitoring to oversee the study and verify that the conduct of the clinical investigation complies with the approved CIP, subsequent amendment(s), ISO14155, and the applicable regulatory requirement(s). There will be a specific person assigned as the Monitor (sec. 1.7).

Julie Tantau will monitor the investigation. She works within the Product Validation group at Bernafon. She is certified in GCP, and familiar with ISO 14155. She has also been certified in Clinical Monitoring and has a CAS I in Clinical Trial Practice and Management.

## 1.4 Signatures

Printed name of Trial Statistician and SAP writer: Christophe Lesimple

| | |
|---|---|
| Place/Date | Signature |

Printed name of Principle Investigator: Barbara Simon

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| Place/Date | Signature |

# 2. INTRODUCTION

The study protocol includes an outline of the statistical methods to be employed in the analysis of the data. The purpose of the Statistical Analysis Plan is to provide full details of the planned statistical methods to be used in the primary report of the trial results. It has been produced in line with the ICH E9 Guidelines and guidelines from Gamble et al. (2017).

## 2.1 Background and Rationale

Amplification and signal processing within hearing aids are designed to mainly improve speech understanding. It is possible to model the acoustical characteristics of speech because they are defined by the human vocal tract characteristics and the articulation speed. This acoustical model of speech is then used as a guideline for optimizing signal processing within the hearing aid.

This approach has shown limitations in terms of perceived sound quality when listening to recorded or live music (Madsen et al., 2015; Looi et al., 2019). Kirchberger & Russo (2016) suggest that the characteristics of music shows more variations than speech in terms of frequency range, sound level, modulation, and dynamic range. The consequence of this larger variability is that no universal model can be used to define a music signal, which, in turn, makes it difficult to define the amplification and signal processing needed for a music program (Greasley et al., 2019). While music already presents a challenge for listeners wearing hearing aids, the challenge might be even more complex for musicians. Vaisberg et al. (2018) highlight that hearing-impaired instrumentalists face challenges in their music activities while wearing hearing aids because there is often little knowledge about individual music practice (music style, instrument range, etc.) or their expectations of music amplification.

The specific topic of hearing aid settings optimized for musicians has not received, to our knowledge, much attention from the research community. Many papers evaluate the effect of hearing loss and music or the effect of hearing aid settings for listening to music, but their design doesn't specifically target hearing-impaired musicians (Mussoi & Bentler, 2015), or the target population for studies is mixed, e.g. with or without musical training, (Kirchberger, 2015). In general, the test design of these trials concentrates on listening to music only, not playing. A single publication, with a focus on hearing aid use while musicians are playing (Vaisberg et al., 2018), supports the need to improve and individualize the fitting of hearing aids for musicians.

The need to optimize the music program is also motivated by:

- The prevalence of hearing loss and associated audiological symptoms among musicians exposed to high sound levels (Di Stadio et al., 2018). This target population could benefit from hearing aids that don't restrict their abilities to play music,
- The benefit (social, cognitive, and physical) of playing music especially for hearing impaired (Leek et al. 2008) and seniors (Lehmberg & Fung, 2010). Music is a multi-sensorial activity which reinforces social and communication skills (Fulford & Ginsborg, 2014). It is therefore important to allow hearing-impaired musicians to continue their musical activities.

## 2.2 Objective and hypothesis

The assumption is that hearing aids that are optimized for hearing-impaired musicians should provide a better experience while playing an instrument with the following consequences: (a) improvement of the perception of music, (b) improvement of the ability to play, and (c) indirect improvement of the quality of life.

The results of the trial will be used to examine the benefit provided by the fitting protocol optimized for hearing-impaired musician (Greasley et al., 2019) compared to the standard fitting approach, as well as identify further optimization of the tested products. In summary, the primary reason for this study is to evaluate the new fitting protocol for musicians using hearing aids. The secondary reason is to evaluate the overall safety of the IMD by testing for unexpected behaviour from the IMD and by the collection of AEs to identify any new risk factors since their release to the market as a post-market quality control.

More specifically, the objective of the trial is to provide answers to following research questions:

- Does the fitting protocol optimized for hearing-impaired musician's individual needs make an audible difference compared to a standard fitting approach?
- Is the fitting protocol optimized for hearing-impaired musician's individual needs preferred over the standard fitting approach?
- Does the fitting protocol optimized for hearing-impaired musician's individual needs improve the perception of music compared to a standard fitting approach?

# 3. STUDY METHODS

## 3.1 General study design and plan

Bernafon AG will carry out testing with musicians who have a hearing loss within the fitting range of the investigational medical device (IMD) in order to validate the performance of the fitting protocol optimized for musicians. The intended purpose of the study is to compare the performance of two different music programs within the IMD which is currently sold on the market. The programs will be referred to as the Investigational Protocol (IP), i.e. a program individually optimized for each participant with his own instrument, and the Standard Protocol (SP), i.e. the default music program provided by the IMD, throughout this document.

For the current study, the IMD is a miniRITE (MNR) behind-the-ear (BTE) style which offers the possibility to the user to select different listening programs. Hearing aid acceptance and overall benefit will first be evaluated using a single general program, fitted during the first visit with a NAL-NL2 fitting rationale (not music specific). The first field period will take place after the first visit and should also ensure that there are no comfort or manipulation difficulties when the participants are using the hearing aids. Musical experiences will be evaluated with the general program during the first visit and the first field test to get the baseline performance of music amplification. The fitting rationale used for the first field test is not designed for music, therefore two additional programs specifically designed for music will be programmed during the second visit and tested during the second field test. One music program

will use the standard protocol (SP) for live music and the other program will use the investigational protocol (IP) (an optimized method for music performance). Each program is accessible via a local control on the IMD housing. Data from the first field test will be used as reference for each subject and data from second field test will be collected to answer the research questions.

A randomised and single-blinded, single-arm design will be used for the field tests, and the lab test order will be randomized and single-blinded. The performance of the different amplification strategies will be evaluated in a controlled environment using a music perception test and during the field test using questionnaires. This approach should cover the range of use cases to better understand the effect of the IP over the SP.

The current trial is a pilot / explorative test because no publication can be directly used for the methodology, sample size calculation, or data analysis. However, cited publications with a relation to the topic (e.g. perception of music, music and hearing aids, music and hearing-impaired listeners, etc) will serve as reference for the trial set-up.

## 3.2 Randomization

The study is based on repeated measures with the SP and the IP. Participants are asked to switch between the listening programs in a given condition (practice, rehearsal, or concert) in order for them to gather comparable experiences while playing and listening to music.

Program allocation effect, i.e. higher likelihood to use program 2 than 3, will be compensate by randomizing the order of the tested protocols in the listening program slot. This risk is outbalanced by the benefit of directly comparing the same listening situation with both programs.

The program order will be randomized, and the lab test order will follow the program order randomization. The active participation of the investigator is required for the IP resulting in a single blind (participant only) design. The randomization list will be provided to the investigator by the statistician and documented before the recruitment process starts.

The randomization list will be generated with a random permuted block method and a random digit link to control any potential order inequality. Pocock (1983, p 77) provides a link between random digits and the structure of blocks for four patients and 2 treatments (order). No stratification is foreseen because no confounding factors have been identified at this stage of the study design.

## 3.3 Sample Size

Vaisberg et al. (2018) is the only publication, to our knowledge, specifically focusing on hearing aids for hearing impaired musicians. They used a qualitative research methodology based on semi-structured interviews with 12 participants. Fullford et al. (2011) and Fullford & Ginsborg (2014) also used 12 participants for qualitative research studies about how hearing-impaired musicians experience sound and communicate while playing music. However, these publications are based on qualitative research methods which cannot be directly used for the sample size estimation.

The list below summarizes the sample sizes and population attributes from quantitative research tests in a lab, i.e. exclusion of questionnaire-based research, with a topic related to the current study:

- Croghan et al. (2014) investigated the preference of signal processing within hearing aids while listening to music with 18 hearing aid users with paired comparisons. Sub-group analysis was made based on the music experience, i.e. 9 listeners in the musician group and 9 listeners in the non-musician group.
- Kirchberger & Russo (2015) compared music perception with the adaptive perception test in the unaided condition with 21 hearing impaired and 19 normal hearing listeners. However, music experience showed great variation among the participants.
- Prentiss et al. (2015) evaluated chord discrimination and timbre perception with listeners presenting the following characteristics: normal hearing, hearing aid user, bi-modal hearing (hearing aid and cochlear implant), and cochlear implants. Each subgroup was composed of 14 participants without indication about their musical activities.
- Mussoi & Bentler (2015) evaluated the effect of a specific signal processing algorithm (frequency lowering) on the sound quality while listening to music using paired comparisons. They recruited 30 normal hearing listeners (15 with and 15 without musical training) and 27 hearing impaired listeners (15 without and 12 with musical training).
- Kirchberger & Russo (2016) evaluated the effect of another signal processing algorithm (dynamic range compression) using the adaptive music perception test. They recruited 31 hearing aid users with varying musical experience (from none to professional musician). From the overall sample, only 14 participants had a positive score regarding their musical experience.

The sample size ranges between 9 and 21 participants when looking at hearing aid users with a certain amount of musical training. This range can be used as a baseline for the sample size definition. However, there are some known limitations when using these references. Their study designs only include tests where the participants listen to predefined music samples and not when they are playing their own musical instruments. The definition of the sample size for this exploratory trial should take the population homogeneity and the recruitment potential into account.

On one hand, arguments for a sample size closer to the lower boundary might be justified by a relative homogeneous population reflecting a strong external validity potential because:

- The hearing loss is within the fitting ranges of the IMD, i.e. exclusion of participants with a too mild or profound hearing loss degree,
- The musical experience and practice are set as inclusion criteria, i.e. participants are regularly playing an instrument in different groups or ensembles,
- The recruitment process is restrictive. The target population must fulfil the inclusion / exclusion criteria and be ready to bring their own instrument for the IP fitting. These criteria will eliminate potential participants with cognitive, social, or physical limitations.

On the other hand, there are some unknown parameters that have also to be considered for the sample size definition:

- The effect of the instrument, i.e. the sound generation principle greatly varies between a string, a woodwind and a brass instrument. This might affect the perception of sound and

interact with the range of the instrument, the hearing loss degree and type,

- The effect of amplification through hearing aids when musicians are playing. All the above-mentioned tests are based on passive listening experience. There are no publications, to the best of our knowledge, about the use of auditory feedback to control the production of music. We can assume that adaptation of their own voice production to the environment (Lombard effect) and perception of sound might show similarities when playing music,
- The effect of the IP which follows guidelines for hearing aids fitted to musicians. The guidelines are based on a project (Greasley et al., 2019) but no results based on quantitative research were published. It is therefore not possible to estimate an effect size when a personalized protocol like the IP is used with musicians.

The uncertainty from the test design and the unknown effect size from the IP motivates the choice for a larger sample size. Regarding recruitment possibilities, based on the principal investigator's input, the sample size was set to 18-20 participants for the current study.

### 3.4 Timing of data analysis

Independent study monitoring will be conducted in adherence to the Good Clinical Practice guidelines before the data are downloaded and transmitted to the statistician. Data cleansing and validation will be performed upon completion of the last visit of the last patient included in the study. The final analysis will be conducted thereafter. Based on the trial design and the risk evaluation, no motivation was identified to conduct an interim analysis.

## 4. STATISTICAL PRINCIPLES

### 4.1 Levels of confidence intervals and p-values

Inferential statistical tests will be performed using the two-sided $\alpha = 0.05$. All reported p-values greater than or equal to 0.001 will be rounded to three decimal places and p-values less than 0.001 will be displayed as "<0.001". Confidence intervals are computed from observed data at 95%.

### 4.2 Analysis populations

The analysis of the primary outcome will be based on the intention-to-treat (ITT). The ITT population will include all participants with associated primary outcome data, excluding only subjects who were deemed ineligible following screening visit, those who withdrew from the trial, were unwilling for their previously collected data to be utilised or those who failed to provide baseline.

## 5. TRIAL POPULATION

The following demographic and baseline characteristics will be tabulated overall for the ITT and per protocol population: Age (years), Gender (categorical variable), Hearing Loss Degree (from/to categories), 4-frequency Pure Tone Average (in dB HL), Acoustical Coupling with the IMD (categorical variable), music experience, and history, i.e. hearing loss onset, ear surgery, otalgia, otorrhea, otitis, tinnitus, and noise exposure.

For continuous variables (e.g. age), descriptive statistics will be presented (mean, standard deviation, median, minimum, maximum, interquartile range and number of participants with data). For categorical variables, the data will be presented using percentages, frequency and number of participants with data. The denominator for the percentages will be the number of patients with non-missing data.

# 6. ANALYSIS

## 6.1 Outcome definitions

### 6.1.1 Primary Objective

The study will assess the performance of the IP in comparison to the SP using a preference questionnaire. After wearing the devices for at least 10 +/-7 days and using them in daily life and various music situations, the subjects will be asked to complete a preference questionnaire and choose between the two music programs (SP and IP).

### 6.1.2 Primary Outcome Measure

The primary outcome is measured with a preference questionnaire in which the subjects must choose which program (IP or SP) they preferred for listening and playing music. They must also state how sure they are of their decision and indicate from a list of qualities upon which their decision is based.

### 6.1.3 Secondary Objectives

The secondary objective is to assess the perception of music with the IP in comparison to the SP using the adaptive music perception (AMP) test (Kirchberger & Russo, 2015). The AMP provides a means to evaluate perception of details in music with various subscales, e.g. pitch, duration, loudness. The hypothesis is that the performance of the IP should not be inferior to that of the SP. Baseline scores for the AMP test are measured unaided and aided with the general listening program, i.e. not specific for music.

Additionally, a music perception questionnaire based on Rutledge (2009) will evaluate the perception of music in various environments with each listening program. Overall hearing aid benefit will be measured with a general product questionnaire

### 6.1.4 Secondary Outcome Measures

Secondary outcomes will be measured with the adaptive music perception (AMP) test. The test uses an adaptive procedure to find the threshold (Levitt, 1971) of different attributes describing music perception. Based on the recommendations of the AMP test developers (Kirchberger & Russo, 2015; Kirchberger, 2015), only the meter and timbre subscales will be measured. Each subscale is described by three low-level dimensions, i.e. level, pitch, and duration for the meter subscale and brightness, attack, and spectral irregularities for the timbre subscale.

Feedback about their specific music experiences will be evaluated for the general listening program and both music specific listening programs, i.e. reflecting the SP and the IP. The music questionnaire is divided into the overall performance (artifacts, intonation, instrument identification, melody and harmony

recognition), performance of amplification with their own instrument (pleasantness, naturalness, and sound fidelity), and performance of amplification with other instruments. The answer format is based on a visual analogue scale completed with the relevant descriptors anchored at the ends and the middle of the scales (Rutledge, 2009).

The overall benefit given by the hearing aid (IMD) will be evaluated with a general product questionnaire. The questionnaire will focus on the performance of the device with specific questions regarding physical comfort, acoustical feedback, and sound quality.

#### 6.1.5 Safety Objectives

The study aims to assess the overall safety of the IMD by testing for unexpected behaviour from the IMD and by the collection of AEs to identify any new risk factors since their release to the market.

#### 6.1.6 Safety Outcome Measures

The questionnaires used for the secondary outcome will also contain questions to measure the safety of the devices. These questions will specifically address unexpected noise or behaviour from the devices. Unexpected behaviour includes unprovoked feedback or whistling, distorted sounds or artefacts, spontaneous muting or the shutting-off of the device, and any unexplained warning signals, beeps, or loud sounds.

### 6.2 Analysis method

#### 6.2.1 Preference Test

The preference score is rated on a 5-points Likert scale: SP much better, SP better, no difference, IP better, IP much better. The score distribution is described by the minimum, median, and maximum values and tested with a Wilcoxon signed-rank test with the assumption that ordinal scores from a Likert scale reflect the within subject difference. The null hypothesis is that there is no difference between the tested protocols and the alternative hypothesis is that there is a preference for one of the tested protocols.

Certainty and motivation of preference will be summarized and described separately. The results of this test will be used to answer the 1$^{st}$ and 2$^{nd}$ research questions.

#### 6.2.2 Adaptive Music Perception (AMP) Test

The AMP test is based on an adaptive procedure that provides the threshold reflecting the amount (time, loudness, pitch…) that each participant can detect above chance. The thresholds are measured on ratio scales: duration in milliseconds, pitch in hertz, loudness in decibels. Kirchberger & Russo (2015) indicate that the thresholds might be influenced by different covariates, like degree of hearing loss or music experience, and by the type of signal processing. Measured thresholds will therefore be modelled by a linear mixed-effect regression with backwards selection based on the variation inflation factor (VIF). This gives a complex picture for the coefficient interpretation as there are 4 test conditions: unaided, aided general program, aided SP, and aided IP. Planned contrasts will be considered:

1. Unaided vs Aided

2. General vs Music-specific programs
3. IP vs SP

The 3rd research question will be answered with a paired t-test on each subscale comparing threshold from the IP to the thresholds from the SP.

#### 6.2.3 Music Specific Questionnaire

The results from the music questionnaire are scores from a visual analogue scale. The distribution of the scores will be visualized with boxplots for each listening program (General, IP, or SP program) and situation (own musical instrument vs other musical instruments). The effect of listening programs and situation will be evaluated with mixed effect regression model taking into account the hearing loss degree, own instrument category (string, woodwind, or brass), and music experience as fixed effects. Planned contrasts will be considered:

1. General vs Music-specific programs
2. IP vs SP

Results from the second contrast will be used to answer the 3rd research question.

#### 6.2.4 General Questionnaire

**Reported acoustical feedback**: it is asked how often they experience acoustical feedback. Answer possibilities range from never to always on a 5-points Likert scale.

**Reported sound quality**: rating of the overall sound quality is reported on a 5-points Likert scale, from excellent to very bad.

Results from both questions will be analysed with Wilcoxon signed-rank test to evaluate if the mean rank differs between conditions.

**Experienced artifacts**, i.e. unexpected sounds or noises must be reported and described individually.

Results from the general questionnaire are used to evaluate the safety of the IMD.

### 6.3 Missing data

Unless specified otherwise in each objective, no statistical techniques will be used to impute missing data. If a subject's data are missing for any reason, that subject will not be included in that portion of the analysis. The number of subjects included in each analysis will be reported so that the potential impact of missing data can be assessed.

### 6.4 Harms / Safety Data

The adverse event risks of taking part in the study have been assessed to be low in the study protocol. Numbers of adverse events and serious adverse events will be cross-tabulated for the IMD and categorised by severity. No formal statistical analysis will be conducted, but AEs and SAEs will be closely monitored throughout the process.

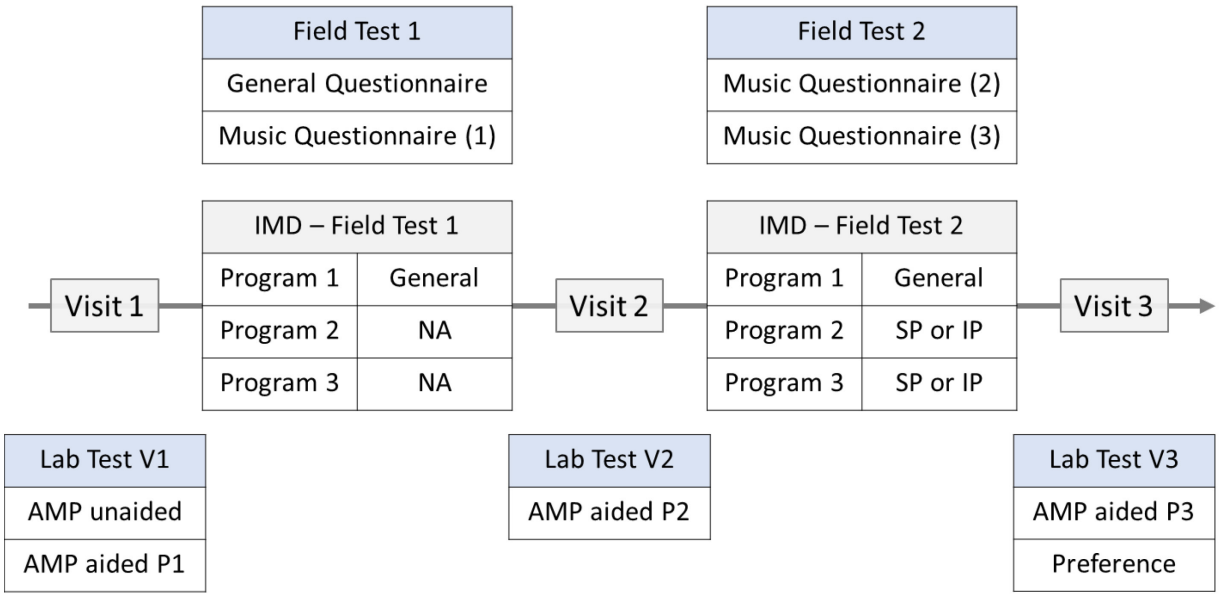
Serious Adverse Events (SAEs) will be recorded and the site will notify the trial monitor of any SAE, who will then notify the project sponsor within one working day.

### 6.5 Statistical software

Data manipulation, statistical summaries and statistical analyses will be performed using R version 3.5.3 or higher.

## 7. TIMELINE FOR VISITS AND OUTCOMES

The timeline for the trial is shown in the figure below. The 3 visits and the 2 field tests are associated to the measured outcomes collected in the lab or in the field.



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