Official Title: A Prospective, Multicentre, Open Clinical Investigation Evaluating Clinical Performance, Safety and Patient Reported Outcomes With an Active Osseointegrated Steady-State Implant System (OSI) in Adult Subjects With Conductive Hearing Loss, Mixed Hearing Loss or Single-sided Sensorineural Deafness

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Statistical Analysis Plan

Clinical Investigation Title:	A prospective, multicentre, open clinical investigation evaluating clinical performance, safety and patient reported outcomes with an Active Osseointegrated Steady-State Implant System (OSI) in adult subjects with conductive hearing loss, mixed hearing loss or single-sided sensorineural deafness.
Clinical Investigation Short Title:	Clinical performance, safety and PROs of an Active Osseointegrated Steady-State Implant System (OSI)
Clinical Investigation Number:	CBAS5751
Related CIP:	D1622635, 2.0
Clinical Project Manager (CPM):	[redacted] Cochlear Bone Anchored Solutions AB Konstruktionsvägen 14 PO Box 82 Mölnlycke, Sweden, SE-435 22 [redacted]
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SAP Version:	1.0
Date:	26-MAR-2020

[redacted]

Contents

1 INTRODUCTION

This document is a companion document to the Clinical Investigation Plan (CBAS5751). It includes a comprehensive description of the sample size estimation, the intended statistical analyses with reference to the primary and secondary hypotheses, and additional statistical considerations such as the intended treatment of missing data.

Any deviation from the Statistical Analysis Plan will be reported in the Clinical Investigation Report.

1.1 Schedule of events

	Screening And Baseline	Surgery	Suture removal	Fitting	Follow up 6W	Follow up 3M	Follow up 6M
Timing of visit		**0**	**2W**	**4W**	**6W**	**3M**	**6M**
Visit window (±)			**±5D**	**±1W**	**± 1W**	**± 2W**	**± 3W**
Procedures							
Written informed consent	X						
Demographics	X						
Eligibility	X						
Medical history	X						
Hearing history	X						
Device history	X						
Audiogram	X[a]						
Soft tissue thickness	X						
Surgery		X[b]					
Suture removal			X				
Sound processor fitting	X[c]			X	X[d]	X[d]	X[d]
Microphone placement				X			
Fine tuning				X	X[d]	X[d]	X[d]
Feedback measurements				X	X[e]	X[e]	X[e]
Coil-to-coil measurements				X	X[e]	X[e]	X[e]
BC Direct	X[f]			X	X[e]	X[e]	X[e]
Free field thresholds	X[f, g]			X		X	X
Speech recognition in quiet	X[f, g]			X		X	X
Speech recognition in noise	X[f, g, h]			X		X	X
APHAB	X[g]					X	X

	Screening And Baseline	Surgery	Suture removal	Fitting	Follow up 6W	Follow up 3M	Follow up 6M
Timing of visit		**0**	**2W**	**4W**	**6W**	**3M**	**6M**
Visit window (±)			**±5D**	**±1W**	**± 1W**	**± 2W**	**± 3W**
SSQ	X[g]					X	X
HUI	X[h]					X	X
Usability				X[i]	X[i]	X[i]	X[i]
Numbness			X	X	X	X	X
Device exposure [j]		X	X	X	X	X	X
Adverse Events	X	X	X	X	X	X	X
Device Deficiencies		X		X	X	X	X
Concomitant therapies	X	X	X	X	X	X	X
Extra visits as needed							

Abbreviations: BC, Bone Conduction; APHAB, Abbreviated Profile of Hearing Aid Benefit; SSQ, Speech, Spatial and Qualities of Hearing Scale; HUI, Health Utilities Index

[a] An audiogram not older than 6 months can be used if it contains all the required frequencies (250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000 and 8000Hz).

[b] Surgical variables: Surgery time, Bone polishing/removal at the actuator site, BI300 Implant length, Location of BI300 Implant, Type of anesthesia, Soft tissue reduction, Surgical incision type, Length of the surgical incision, Placement of the coil, Soft tissue thickenss, Location of surgical incision

[c] Should be performed with Baha 5 Power at Screening and Baseline

[d] Should be done if needed.

[e] Should be performed at each occasion the software is being used to fit or fine tune the device

[f] Baha 5 Power Sound Processor on Baha Softband.

[g] Unaided.

[h] In a preoperative hearing situation

[i] Usability: Magnet choice, Sound Processor retention, Sound Processor wearing comfort at first fitting and all follow up visits, Daily use, Daily streaming, Battery life time, Use of SoftWear pad at all follow up visits.

[j] "Device exposure" is to collect information about for how long the subject is exposed to the Osia 2 Sound Processor and Osia 2 Implant. Data is summarized from other case report form pages.

2 STUDY POPULATION

The rationale for conducting this clinical investigation is to gather clinical data on patients implanted with the OSI200 Implant. While the non-clinical and clinical data all indicate that the Osia 2 System will perform as intended and provide a bone conduction hearing implant (BCHI) system with a similar, or improved, safety profile as its CE-marked predecessor device, which is currently being used by more than one hundred recipients world-wide, it is of utmost interest to assess the performance and safety of the Osia 2 System when used as intended.

The following sites will be participating in the study.

Site	Planned number of patients
The Royal Victorian Eye and Ear Hospital	10-15
Sydney Cochlear Implant Centre	10-15
Department of Otorhinolaryngology, Head and Neck Surgery, Faculty of Medicine, The Chinese University of Hong Kong	10-15

Subgroup analyses will also be performed on one group consisting of Mixed/conductive subjects and one consisting of SSD subjects.

3 STATISTICS

3.1 Sample Size

Based on 6 months safety data from 51 subjects implanted with the predecessor Osia System at 5 clinics in the multicentre clinical investigation described in section 4.2.2.1 it is judged that approximately 10 subjects per clinic and 3 clinics is reasonable for detecting any safety issues with the Investigational device in this study. The primary safety evaluation will be performed 3 months post-surgery, which with an estimation of 30 subjects will equate 7.5 patient years. This is considered to be enough safety data for the primary safety analysis.

With a total of 30 subjects, there will be a very high power to detect significant changes in the primary performance evaluations audiometric thresholds (PTA4) and adaptive speech in noise (speech to noise ratio, SNR) at 3 months.

PTA4: Assuming the same mean reduction in PTA4 as in the multicentre clinical investigation of the predecessor Osia System (Mean change -25 dB, SD 9.5 dB), the resulting power with 30 subjects is 0.99.

SNR: In the multicentre clinical investigation of the predecessor Osia System a change in SNR from 4.98 dB (SD 7.76 dB) unaided to -8.19 dB (SD 6.58 dB) aided resulted in a mean improvement in SNR of -13.3 dB (SD 8.1 dB). In that investigation, speech was presented from the front and noise from the rear speaker. In the present investigation, however, both speech and noise will be presented from the front speaker, which is known to result in higher SNR values in the aided situation (the SNR in the unaided situation is not expected to change significantly). In a pilot clinical investigation conducted at Cochlear's own research facility (CBAS5271, Sub study 118), a mean SNR value of -2.5 dB was recorded

with the Investigational device (Osia 2 System). Assuming that in the present investigation the unaided mean SNR is similar to the unaided scores in the multicenter investigation and that the aided mean SNR is similar to the pilot investigation, a mean improvement in SNR of approximately -7.6 dB (SD 8.1 dB) is expected. With 30 subjects, the resulting power is 0.99.

3.2 Analyses

3.2.1 Pass/Fail Criteria

Not Applicable.

3.2.2 Hypotheses

The hierarchical testing procedure below is introduced to guarantee that the probability of Type I error is < 5% for all confirmative statements. The order of the hierarchical testing procedure will be:

1. PTA 4 pre-operative unaided vs. 3 months post-surgery (Primary efficacy analysis)
2. Adaptive speech recognition in noise (50% performance), signal to noise ratio (SNR) pre-operative unaided vs. 3 months post-surgery
3. Speech in quiet at 65dB SPL pre-operative unaided vs. 3 months post-surgery
4. APHAB Global pre-operative unaided vs. 3 months post-surgery
5. Hearing attribute (HUI) pre-operative situation vs. 3 months post-surgery
6. Mean of the 12 items (Total score) in the SSQ pre-op unaided vs. 3 months post-surgery

If the first analysis is significant the probability mass 0.05 will go to the second analysis. If the second analysis is also significant the probability mass 0.05 will go to the third analysis and so on. When the first non-significant analysis is reached this and all analyses thereafter will be non-confirmative while the previous analyses will be confirmative. If the first analysis is non-significant no analysis will be confirmative. All testing will be Alpha level of 0.05 and two-sided test will be used and the analysis will be performed on the ITT.

3.2.3 Primary Hypotheses

Group mean free-field PTA4 (average of 500, 1000, 2000, and 4000 Hz) with the Investigational device at the 3-month postoperative interval will be improved over that measured preoperatively in the unaided condition (baseline).

This endpoint is represented by the following hypotheses:

H_0: $\mu_F - \alpha_0 = 0$,

H_a: $\mu_F - \alpha_0 \neq 0$,

where:

α_0 = baseline preoperative PTA4;

μ_F = mean follow-up PTA4 3 months postoperative.

[redacted]

Change in free-field threshold audiometry: PTA4 (mean of 500, 1000, 2000 and 4000Hz), from unaided versus Investigational device at 3 months post-surgery visit for the ITT population, using Fisher's two-sided non-parametric permutation test for paired observations to demonstrate an improvement in PTA4.

Alpha level of 0.05 and two sided test will be used and the analysis will be performed on the ITT population.

Group mean Adaptive speech recognition in noise (50% performance), speech to noise ratio (SNR) with the Investigational device at the 3-month postoperative interval will be improved over that measured preoperatively in the unaided condition.

This endpoint is represented by the following hypotheses:

H_0: $\mu_F - \alpha_0 = 0$,

H_a: $\mu_F - \alpha_0 \neq 0$,

where:

α_0 = baseline preoperative Adaptive speech recognition in noise (50% performance), speech to noise ratio (SNR);

μ_F = mean follow-up Adaptive speech recognition in noise (50% performance), speech to noise ratio (SNR) 3 months postoperative.

Change in Adaptive speech recognition in noise (50% performance), from unaided versus Investigational device at 3 months post-surgery visit for the ITT population, using Fisher's two-sided non-parametric permutation test for paired observations to demonstrate an improvement in PTA4.

Alpha level of 0.05 and two sided test will be used and the analysis will be performed on the ITT population.

Both PTA4 and SNR must be significant at alpha 0.05 for the primary analysis to be considered as confirmative.

Missing data will be handled according to 3.4.1.

3.2.4 Secondary Hypotheses

Group mean **Speech in quiet at 65dB** when using the Investigational device at 3 months postoperative compared to the unaided hearing using Fisher's two-sided non-parametric permutation test for paired observations.

This endpoint is represented by the following hypotheses:

H_0: $\mu_F - \alpha_0 = 0$,

H_a: $\mu_F - \alpha_0 \neq 0$,

where:

α_0 = baseline preoperative word recognition score;

μ_F = mean follow-up word recognition score 3 months postoperative.

Group mean **Global score using the Abbreviated Profile of Hearing Aid Benefit (APHAB)** when using the Investigational device at 3 months post surgery compared to

unaided hearing, using Fisher's two-sided non-parametric permutation test for paired observations.

This endpoint is represented by the following hypotheses:

H_0: $\mu_F - \alpha_0 = 0$,

H_a: $\mu_F - \alpha_0 \neq 0$,

where:

α_0 = baseline APHAB Global score;

μ_F = mean follow-up APHAB Global score 3 months postoperative.

Group mean **Hearing attribute (HUI)** when using the Investigational device at 3 months post surgery compared to the preoperative hearing situation, using Fisher's two-sided non-parametric permutation test for paired observations.

This endpoint is represented by the following hypotheses:

H_0: $\mu_F - \alpha_0 = 0$,

H_a: $\mu_F - \alpha_0 \neq 0$,

where:

α_0 = baseline Hearing attribute (HUI);

μ_F = mean follow-up Hearing attribute (HUI) 3 months post-fitting.

Group mean **Total score using the Speech, Spatial and Qualities of Hearing Scale (SSQ)** when using the Investigational device at 3 months post surgery compared to the unaided hearing, using Fisher's two-sided non-parametric permutation test for paired observations.

This endpoint is represented by the following hypotheses:

H_0: $\mu_F - \alpha_0 = 0$,

H_a: $\mu_F - \alpha_0 \neq 0$,

where:

α_0 = baseline SSQ Total score;

μ_F = mean follow-up SSQ Total score 2 months post-fitting.

Missing data will be handled according to 3.4.1.

All other secondary outcomes will not be formally hypothesis tested but summarized and p-values will be calculated.

In addition to comparing follow up data with unaided analyses will also be made with Baha Power sound processor on a Baha Softband (screening).

3.2.5 Additional statistical issues

If any paired analysis of dichotomous and ordered categorical variables (i.e. if any continuous variables will be categorized) will be made the Sign test will be used.

The main efficacy analyses will be performed at 3 months after surgery on the ITT population and complementary efficacy analyses will be performed 6 months after surgery on the ITT population. In addition, all analyses will be made on the PP population. Sub analyses will also be performed on one group consisting of Mixed/conductive subjects and one consisting of SSD subjects.

Primary safety analysis will be performed at 3 months post-surgery.

3.3 Analysis Datasets

The final definition of the analysis sets (ITT, PP and Safety) will be taken at the clean file meeting before database lock.

All efficacy analyses will be performed on both ITT and PP populations.

3.3.1 Safety

The Safety population/dataset consists of all surgically treated subjects.

3.3.2 Intent-to-Treat

The Intention-to-Treat population/dataset (ITT) will include all subjects who have undergone surgical intervention.

Missing data will be handled according to 3.4.1.

3.3.3 Per Protocol dataset

The Per Protocol population/dataset (PP) will include subjects that have completed the study according to the protocol. Subjects that were incorrectly included or were considered major protocol violators that affect the primary analysis should be removed from the PP population/dataset.

Missing data will be handled according to 3.4.1.

3.4 Additional Statistical Considerations

3.4.1 Missing, Unused or Spurious Data

All ITT analyses will be performed/presented both for the imputed (main analyses) and for the non-imputed data (sensitivity analyses).

Imputation of missing values will be performed for all efficacy variables. No imputation of baseline values or baseline carry forward will be made. Imputations will be made according to the following rules:

1. If a value is missing at the end of a time period for a patient, last observation will be carried forward.
2. If a missing value is occurring between two time points with values, an interpolation will be made for continuous variables and for categorical variables the value from the previous visit will be carried forward.
3. As a sensitivity analysis imputation of missing values will be performed for all efficacy variables using stochastic regression imputations.

Spurious data will be cleaned prior to clean file meeting. If spurious data are detected after clean file is declared actions to consider will be;

1. unlock, correction of the spurious data and a new re-lock will be made alternatively,
2. a sensitivity analysis will be performed that accounts for the spurious data in a proper statistical fashion (e.g. non parametric methods).

3.4.2 Planned Interim Analysis

No interim analyses are planned to be performed.

3.4.3 Criteria for Termination of the Clinical Investigation

Not applicable.

3.4.4 Additional Statistical Analyses

3.4.4.1 Major protocol deviations

Major protocol deviations are those that are considered to have an effect on the analysis. The number of patients with major protocol deviations will be summarised per treatment group. A list of protocol deviations will be produced.

3.4.4.2 Demographics

A descriptive presentation of demographic data will be presented as described in paragraph 3.7:

- Age collected as date of birth (month and year)
- Gender
- Race
- Tobacco use
    - Never /Current/Former
    - Primary method (Cigarettes/Cigars/Pipe/eCigarettes/Chewing/Other)
    - Cigarettes/day

3.4.4.3 Medical history

A descriptive presentation of medical history will be presented as described in paragraph 3.7:

- Relevant medical and surgical treatment during the past three years as judged by the investigator
- Current concomitant medication and treatments

3.4.4.4 Hearing history

Test ear (right/left)

A descriptive presentation of hearing history will be presented as described in paragraph 3.7:

- Type of hearing loss:
    - Conductive,
    - Mixed,
    - SSD
- Aetiology of hearing loss:

- (chronic) infection,
- tumour,
- trauma,
- malformation,
- otosclerosis,
- genetic
- unknown
- other

- History of hearing loss
  - progressive
  - progressive with sudden
  - sudden
  - congenital with progression (if age at onset was 0 month)
  - congenital without progression (if age at onset was 0 month)

3.4.4.5 Device history

Hearing aid

- Has the subject used hearing aid (never/current/former)
- Has the subject used hearing aid (never/current/former) on test side
- Has the subject used hearing aid (never/current/former) on non-test side
  Has the subject used hearing aid (never/current/former) on both test side and non-test side

Hearing Implant

- Does the subject have and audiological implant (Never implanted/Implanted, still in use/Implanted, not in use/Explanted)
- Does the subject have and audiological implant (Never implanted/Implanted, still in use/Implanted, not in use/Explanted) on test side
- Does the subject have and audiological implant (Never implanted/Implanted, still in use/Implanted, not in use/Explanted) on non-test side
- Does the subject have and audiological implant (Never implanted/Implanted, still in use/Implanted, not in use/Explanted) on both test side and non-test side

All information collected in the eCRF regarding hearing aid and hearing implant will be listed.

3.4.4.6 Audiogram

A descriptive presentation of audiograms at Screening will be presented (tabulated and graphically) as described in paragraph 3.7 by frequency (and Pure Tone Average (PTA4) for CHL and MHL (*mean of 500, 1000, 2000 and 4000Hz*) and for SSD (*mean of 500, 1000, 2000 and 3000Hz*)), test side, air/bone and masked/unmasked.

3.4.4.7 Soft tissue thickness

A descriptive presentation of Soft tissue thickness will be presented as described in paragraph 3.7.

3.4.4.8 Surgery

A descriptive presentation of surgery data will be presented as described in paragraph 3.7:

- Treatment ear (indicate left or right or both. In case of both, indicate “test ear”).
- Soft tissue thickness (mm)
- Type of anesthesia (general/local)
- Bone polishing/removal at the actuator site (yes/no)
- BI300 Implant length (3mm/4mm)
- Location of BI300 Implant (mm)
- Soft tissue reduction (yes/no)
- Surgical incision type (examples; C-shaped/S-shaped/straight)
- Location of the surgical incision in relation to the actuator (anterior/posterior)
- Estimated length of the surgical incision (mm)
- Placement of the coil
    - periosteal pocket (under periosteal)
    - on top of periosteum
    - on top of muscle
- Surgery time (time between first incision to last suture)

3.4.4.9 Usability

A descriptive presentation of surgery data by visit will be presented as described in paragraph 3.7:

- Magnet choice
- Sound Processor retention
- Sound Processor wearing comfort
- Use of SoftWear pad
- Daily use
- Daily streaming
- Battery lifetime
    - Did the “low battery” signal occur (yes/no)

3.4.4.10 BC Direct

A descriptive presentation of surgery data by visit will be presented as described in paragraph 3.7:

- BC Direct [0.25, 0.5, 0.75, 1.0, 1.5, 2.0, 3.0, 4.0 and 6.0 kHz] will be performed using a Baha Softband (preoperatively) at screening/baseline and using the Investigational device at fitting, 3- and 6-months post-surgery.

3.4.4.11 Preoperative hearing aid

The difference in hearing performance at fitting- 3- and 6 months post-surgery when using the Investigational device compared to a preoperative hearing aid (if used by the patient) assessed as:

- The difference in Adaptive speech in noise [signal-to-noise ratio, 50% speech understanding].

3.4.4.12 Coil-to-coil measurement

DLC measurements through-out the study will be presented.

3.4.4.13 Implant site evaluation (numbness)

Implant site evaluation (numbness) will be summarised by frequency and percent of:

1. No numbness,
2. Numbness over the implant Magnet Assembly area and
3. Numbness over the implant Magnet Assembly area and 2 cm outside the implant Magnet Assembly area by visit.

3.4.4.14 Adverse events

Separate tabulations of AEs, ADEs, SAEs, SADEs and AESIs will be produced. AEs, ADEs and AESIs will also be produced by severity (mild, moderate or severe) and relationship (related defined as Possibly, Probably and Definitely related). Number of events, number of subject and percent with events by System Organ Class (SOC, CTCAE) and CTCAE term will be presented.

3.4.4.15 Device deficiency

DDs will be reported by visit as described in paragraph 3.7.

3.4.4.16 Concomitant medication

Concomitant medications will be defined as start or end date from surgery to end of study and will be presented by listings.

3.5 Conduct of Statistical Analysis

The statistical analyses will be performed at Statistiska konsultgruppen by personnel employed at Statistiska konsultgruppen under supervision of [redacted] The analyses will be performed by using SAS 9.4 (or later).

3.5.1 Timing of analyses

The first reporting of analyses will be made when all patients have completed their 3 months visit of the data up to 3 months. This analysis is regarded as the primary analysis. At the end of the study, at 6 months, the second and final reporting of the study will be made including all data up to the 6 months visit including data prior to the 3 months visit (ie all data in the study).

3.6 Quality control on statistical analysis

Each programmer is responsible to continuously during working with data generation programs and statistical programs

3.7 Presentation of data

3.7.1 General

All data will be presented in summarized tables. The distribution of continuous variables as well as change in continuous variables will be given as n, mean, SD, SEM, Median, Min and Max and the distribution of dichotomous and categorical variables will be given as number and percentages. For continuous variables estimated mean and the 95% two-sided confidence interval (bootstrapped) for difference between groups will be presented. The hypotheses' p-values and the corresponding/accompanying estimated with a 95% Ci will be presented where applicable.

Selected variables will be presented in figures showing either box plots or mean (95% CI) over time on actual values and/or change. Audiogram data will be presented as traditional audiograms.

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4 REFERENCES

4.1 Internal References

ID	Document Title	Number

4.2 External References

ID	Document Title	Number

5 CHANGE HISTORY

Version	Change	Author	Date
1.0	Introduction of document	[redacted]	26-MAR-20

6 DEFINITIONS

Term	Description
APHAB	Abbreviated Profile of Hearing Aid Benefit
BCHI	Bone conduction hearing implant

Term	Description
CHL	Conductive Hearing Loss
dB	Decibel
DLC	Digital Link Calibration
HUI	Health Utilities Index
Hz	Hertz
ITT	Intention to treat
Max	Maximum
MHL	Mixed Hearing Loss
Min	Minimum
n	Number
OSI	Active Osseointegrated Steady-State Implant System
PP	Per protocol
PTA4	Pure Tone Average for and (mean of 500, 1000, 2000 and 4000Hz). Different definitions for audiogram on MHL/CHL/SSD patients.
SD	Standard deviation
SEM	Standard error of the mean
SNR	Speech to noise ratio
SSD	Single sided deafness
SSQ	Speech, Spatial and Qualities of Hearing Scale