A prospective, multi-center, single-arm, clinical investigation of the safety and performance of the Sentio system in users with mixed/conductive hearing losses and single sided deafness

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The main objectives of this study will be to demonstrate that the Sentio system improves hearing on the implanted ear and provides patients with improved speech recognition on the implanted ear. In addition, adverse events related to the Sentio…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hearing disorders
Study type	Interventional

Summary

ID

NL-OMON51025

Source
ToetsingOnline

Brief title
BC101 - Safety and performance of the Sentio system

Condition

- Hearing disorders

Synonym
hearing disability, hearing impairment

Research involving
Human

Sponsors and support

Primary sponsor: Oticon Medical AB
Source(s) of monetary or material Support: The research is funded by the company Oticon Medical AB (Askim;Sweden).

Intervention

Keyword: Active transcutaneous, Boneconduction, Implantable hearing system, Sentio

Outcome measures

Primary outcome

The co-primary endpoints are:

Functional gain with Sentio system, i.e. the difference between pre-operative unaided and aided sound field thresholds assessed 3 months post-surgery, on the implanted ear. The functional gain is calculated as the average of frequencies 500, 1000, 2000 and 4000 Hz (PTA4).

Difference in speech recognition score in percent between Sentio assessed 3 months post-surgery and pre-operative unaided condition, measured in quiet on the implanted ear.

MRI sub-study:

Subject's experience of underging an MRI scan with regards to the implant site (e.g. pain and pressure) and overall experience (e.g. claustrophobia).

Radiologist's experience of conducting the scan on patients with a Sentio Ti implant, and complications and mitigating actions.

Secondary outcome

Functional gain (PTA4) on the implanted ear at fitting, 6-, 12- and 24-months post-surgery.

Functional gain on the implanted ear for frequencies: 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz at fitting, 3-, 6-, 12- and 24-months post-surgery.

Aided threshold on the implanted ear for frequencies: 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz at fitting, 3-, 6-, 12- and 24-months post-surgery.

Speech recognition score in percent on the implanted ear assessed in quiet at 3-, 6-, 12- and 24-months post-surgery.

Difference in speech recognition score in percent between Sentio assessed 6- and 12-months post-surgery and pre-operative unaided condition, measured in quiet on the implanted ear.

Signal to noise ratio (SNR) for speech intelligibility in noise with Sentio at fitting, 3-, 6-, and 24-months post-surgery on the implanted ear

Effective gain (PTA4) assessed 3 months post-surgery on the implanted ear.

Effective gain for frequencies 500, 1000, 2000, 3000, 4000 Hz, assessed 3 and 6

months post-surgery on the implanted ear.

Difference in aided thresholds (PTA4) between Ponto on softband preoperatively and the Sentio system assessed 3 months post-surgery, on the implanted ear.

Difference in aided thresholds on individual frequencies (250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz) between Ponto on softband preoperatively and the Sentio system assessed 3 months post-surgery, on the implanted ear.

Difference in speech intelligibility in noise (SNR in dB) between Ponto on softband preoperatively and the Sentio system assessed 3 months post-surgery, on the implanted ear.

GBI score at 3 months post-surgery

IOI-HA score at 6 months and 24 months post fitting

Difference in SSQ12 score between Sentio 3 months and 12 months post-surgery and pre-operative unaided condition

Difference in HUI score between baseline, 3 months and 12 months

Evaluation of satisfaction, usability and comfort at 3 months post-surgery as measured by Sentio Q

Tabulations of retention at 3-, 6-, 12- and 24-months post-surgery as measured by Sentio Q

The proportion of subjects with a functional gain > 0 dB at 3 months (co-primary endpoint)

The proportion of subjects with an improvement in speech recognition score > 0 % at 3 months compared to unaided (co-primary endpoint)

Outcomes A1-2,5, B1-2, C1-3, D1-4 analyzed as the proportion of subjects whose performance is better at the pre-to-postoperative comparisons.

Difference in speech intelligibility in noise (signal to noise ratio, SNR in dB) between the unaided condition and Sentio system, assessed at 3 months and 24 months.

Tabulated surgeries not completed due to insufficient bone thickness and/or unexpected anatomy

Average surgical time in minutes

IPS score at baseline fitting visit and 3-, 6-, 12- and 24-months post-surgery

The level of subject reported pain around the implant measured by a NRS

(numerical rating scale) at fitting, 3-, 6-, 12- and 24-months post-surgery

The level of subject reported numbness around the implant measured by a NRS (numerical rating scale) at fitting, 3-, 6-, 12- and 24-months post-surgery

Rate in percent of incision wound healed as judged by the investigator surgeon at 2 weeks post-surgery

Rate in percent of incision areas swollen as judged by the investigator surgeon at 2 weeks post-surgery

Magnet strength measured on the subject*s heads in Newton at fitting, 6 weeks, 3-, 6-, 12- and 24-months post-surgery

Tabulation of magnets used in the Sentio SP at the time of fitting, 6 weeks, 3-, 6-, 12- and 24-months post-surgery

Self-reported usage hours per day, 3- and 24-months post-surgery.

Average power-on time in hours per day, read from Sentio 1 via Genie Medical BAHS, 3- and 24-months post-surgery.

Tabulated adverse events and serious adverse event related to the device reported from surgery throughout the investigation reported at 6 months

post-surgery.

Tabulated adverse events and serious adverse event related to the device reported from surgery throughout the investigation reported at end of investigation.

Difference in BC-thresholds at individual frequencies (dB) between pre-operative and 6 weeks, 6 months, and 12 months post-surgery measurements for the implanted ear.

Proportion of subjects with at least one frequency with a difference of >10 dB between pre-operatively and post-operative BC threshold, assessed at 6 weeks, 6 months, and 12 months post-surgery

Information gathered from surgery

Information gathered from sound processor fitting

Study description

Background summary

This prospective, multi-centre study funded by Oticon Medical AB will be conducted at six hospitals across Europe (UK, Germany and the Netherlands). In the Netherlands, the study will be performed at two sites (University Medical Center Groningen and Radboud University Medical Center in Nijmegen). This is a pre-market authorisation activity, a regulatory requirement before medical device manufacturers can put products on the market. Patients with a hearing

loss already planned for treatment with a bone-anchored hearing system (BAHS) will be included in the study. 16 to 20 patients will be included in the Netherlands and the total number of patients in the study will be 50. Participation is completely voluntary and the decision to participate must be well-founded and well-informed. The purposes of this study are to investigate the safety and performance of the Sentio system, which is a new transcutaneous bone conduction hearing system (an implant, an external sound processor and accessories) for people with certain types of hearing losses. The implant is implanted into the bone behind the ear (mastoid and temporal bone area). After a period of skin healing a sound processor which transmits sound waves to the implant can be magnetically attached. The implant transforms sound waves to vibrations which are then transmitted to the inner ear via the bone. The (combined) primary objectives are to demonstrate that this device improves the hearing on the implanted ear and makes it easier to recognize speech, compared to the unaided situation. The study includes ten visits to the clinic* one before surgery, the surgery visit, and eight follow-up visits (last visit 24 months after surgery). At the follow-up visits, the skin above the implant will be examined and hearing outcomes will be measured and assessed. Complications and adverse events will be collected. Subjective evaluation of quality of life will be performed via validated questionnaires.

MRI sub-study:
This is an amendment to the BC101 clinical investigation. The original BC101 aims to investigate the safety and performance on the Sentio system. This amendment concerns a sub-study within the original clinical investigation, aiming at exploring the experience of undergoing and MRI scan with implant in situ. The sub-study is conducted in a sub-group of volunteering patients already enrolled in the BC101 study.
MRI is a commonly used diagnostic tool for various purposes and it is important to consider the MRI safety and compatibility of implantable systems and devices. There is a high probability for patients with implantable hearing systems that they will be in need for an MRI investigation in the future.

Study objective

The main objectives of this study will be to demonstrate that the Sentio system improves hearing on the implanted ear and provides patients with improved speech recognition on the implanted ear. In addition, adverse events related to the Sentio system will be evaluated.

Other objectives of the study will be:
To assess the performance of the Sentio system throughout the investigation.
To assess the degree the Sentio system compensates for the bone conducting hearing loss on the implanted ear.
To compare the performance of the Sentio system to a comparator device (latest Ponto SP on softband).
To assess the subjective experience in terms of quality of life, benefit,

patient satisfaction, usability and retention of the Sentio system.
To evaluate performance on individual level.
To demonstrate that the Sentio system provides single-sided deaf patients with improved speech recognition in noise.
To confirm feasibility of performing implantation surgery without pre-op imaging planning (eg. CT-scanning).
To evaluate the duration of surgery.
To assess skin condition in the implant area after implantation with the Sentio system.
To assess the retention force between sound processor and implant.
To assess the usage time with Sentio 1.
Demonstrate that the Sentio system does not lead to deteriorated hearing in the implanted ear.
To compile surgical information input to increase knowledge of transcutaneous system.
To compile fitting data from the fitting of Sentio SP to increase our knowledge and to provide input to further development of transcutaneous solutions.

MRI sub-study:
The objective of this sub-study is to investigate the patient*s subjective experience of undergoing an MRI with the Sentio Ti implant in situ, as well as the radiologist*s experience of conducting the MRI examination.

Study design

This will be a prospective, multi-center, single-arm study on the Sentio system. A maximum of 50 study participants who meet study eligibility criteria will be enrolled. The first subject is expected to be enrolled during October 2021. The expected duration of each subject*s participation is approximately 26 months. The final clinical investigation report is expected to be finalized during Q4 2025.

The justification of the clinical investigation is based on a clinical evaluation of clinical data concerning safety and performance of the investigational device and similar devices. This clinical evaluation resulted in the need for a pivotal clinical investigation to establish the clinical safety and performance of the investigational device and to demonstrate that the device performs as intended under anticipated conditions of use. The clinical investigation is designed to mimic clinical routine practice for similar bone conduction hearing devices as much as possible, to lessen the burden on subjects and staff, but still providing robust and reliable clinical data supporting the research objectives. For performance-related objectives only standardized and well-proven measurement methodologies within audiology will be used. The safety-related objective will be met by continuous collection and evaluation of adverse events throughout the whole duration of the investigation, i.e. 24 months, adding to safety information already known or anticipated. In order to further evaluate the potential impact on

self-reported quality of life, a set of validated questionnaires will be distributed to subjects at different time point during the investigation. Finally, a sponsor developed questionnaire will be distributed to subjects to further evaluate usability aspects not captured or verified by other means.

Below is a summary of all study related procedures which will be performed during the different study visits.

Procedures performed at screening assessment
All patients considered as suitable for a bone-conduction hearing device, similar to the one under investigation, will be approached for participation by their ENT-specialist. At the screening assessment informed consent will be collected after which the screening procedures may be performed. During the first screening visit inclusion and exclusion criteria will be assessed. Further medical and surgical history will be collected, and skin status assessed by the surgeon. During the second screening visit the subject will meet with the audiologist where an audiogram will be performed. Inclusion and exclusion criteria will be further assessed. If the candidate is found eligible for participation baseline measurements for pre-op condition, unaided as well as with a Ponto Sound Processor on a softband, will be conducted. Screening visit 1 and 2 may be performed on the same day.

Surgery
Installation of the Sentio implant in the temporal bone (i.e. slightly behind the ear) is made under local or general anaesthesia. The procedure is estimated to 1 hour. During the surgery, surgical information including time of surgery, soft tissue thickness, depth of bone recess, type of anaesthesia, location of the Sentio implant and incision type will be recorded. Any intra-operative event will be reported.
Any adverse events occurred since screening visits will be recorded.

Surgery follow-up
Two-weeks after surgery, the subject will attend the surgical follow-up visit to assess skin status such as healing and swelling and to follow up on any post-operative events. Any adverse events will be recorded.

Sound processor (SP) fitting
Sound processor fitting will take place one month (+/- two weeks) after surgery, when the skin is healed. The SP fitting visit will include magnet choice- and force measurement, clinically relevant fitting activities in Genie Medical (i.e fitting software), instruction of use and practice in operating the sound processor. Any adverse events will be recorded.

6 Weeks Visit
6 weeks after surgery the subjects will have a follow-up visit. During this visit a clinical assessment of the skin and a subjective pain and numbness assessment is performed. In addition, a magnetic evaluation, audiometry and

usability measurements are performed. Any adverse events will be recorded.

3 Month Visit
3 months after surgery the subjects will have a follow-up visit. During this visit performance evaluation of the Sentio System will be performed, including audiometry, speech recognition and magnetic retention evaluation. Clinical assessments including skin assessment and subjective pain and numbness assessment are performed. In addition, Patient Reported Outcomes (PROs) to assess the subjects* experience and satisfaction with the investigational device will be collected. There will also be PROs concerning usability and appearance of the device, as well as retention of the device. Any adverse events will be recorded.

6 Month Visit
6 months after surgery the subjects will have a follow-up visit. During this visit performance evaluation of the Sentio System will be performed, including audiometry, speech recognition and magnetic retention evaluation. Clinical assessments including skin assessment and subjective pain and numbness assessment are performed. In addition, Patient Reported Outcomes (PROs) to assess the subjects* experience and satisfaction with the investigational device will be collected. There will also be PROs concerning usability and appearance of the device, as well as retention of the device. Any adverse events will be recorded.

12 Month Visit
12 months after surgery the subjects will have a follow-up visit. During this visit performance evaluation of the Sentio System will be performed, including audiometry, speech recognition and magnetic retention evaluation. Clinical assessments including skin assessment and subjective pain and numbness assessment are performed. In addition, Patient Reported Outcomes (PROs) to assess the subjects* experience and satisfaction with the investigational device will be collected. There will also be PROs concerning usability and appearance of the device, as well as retention of the device. Any adverse events will be recorded.

24 Month Visit
24 months after surgery the subjects will have a final follow-up visit. During this visit performance evaluation of the Sentio System will be performed, including audiometry, speech recognition and magnetic retention evaluation. Clinical assessments including skin assessment and subjective pain and numbness assessment are performed. In addition, Patient Reported Outcomes (PROs) to assess the subjects* experience and satisfaction with the investigational device will be collected. There will also be PROs concerning usability and appearance of the device, as well as retention of the device. Any adverse events will be recorded.
Subjects will from now on be treated according to the clinics standard practice for bone-conduction hearing devices.

MRI sub-sudy:
Subjects volunteering for the MRI sub-study will undergo an MRI examination of the head and neck region according to clinical practice and standard operating procedure at the clinic conducting the MRI examination, while adhering to the MRI Safety Information for the Sentio Ti implant. The participation in the MRI sub-study is one visit, which will take up to 45 minutes.
Data on the MRI equipment used, and specific settings applied for each individual patient will be registered in the Electronic Data Capture (EDC) system used for the BC101 clinical investigation.
Immediately after the scan, the participant will be asked to complete a questionnaire about their experience with the MRI examination. Likewise, the radiologist conducting the MRI examination will be asked to complete a questionnaire immediately after the examination has been conducted.

Intervention

The intervention in this study is the Sentio system, which is a Bone Anchored Hearing Systems (BAHS).

BAHS have been available for several years and more than 200,000 implantations have been performed around the world. BAHS uses the natural sound conducting properties of bone. In the Sentio system the sound is transmitted from an external sound processor to an implant under the intact skin. The implant then generates vibrations that is transmitted to the inner ear via the skull bone.

Study burden and risks

Apart from undergoing treatment with this new device, an additional 2-3 visits to the clinic, magnet removal force measurements and the completion of questionnaires are the only additional things in the study compared to normal practice.

The risks associated with the use of the Sentio system are similar to the risks of other transcutaneous bone conduction hearing systems already available on the market.

In order to mitigate risks in association with the Sentio system the following measures have been taken:

•The Sentio Ti implant will be implanted by experienced ENT specialists with knowledge and training ensuring appropriate patient recruitment, effective patient care and follow-up. The Sentio 1 sound processor will be fitted by audiologists. All the participating ENT specialists and audiologists performing the investigation will receive extensive training in the use of the Sentio system.

•The Sentio system is extensively tested for reliability and biocompatibility to ensure the design of a reliable and safe product.

•Participants in the investigation will attend frequent follow-up visits to monitor the safety and performance of the product. This will allow the detection of any complications at an early stage and the possibility to take appropriate mitigating action. The subjects will have the opportunity to frequently interact with the treating physician as well as audiologists and the assessments performed at the visits are non-invasive and closely follows clinical practice. All procedures, investigations and outcome measures in the clinical trial are standard methods used in the field of hearing research and audiology, and there are no procedures or investigations in the trial that add additional risks to the patients.

•The ability to abort the procedure and explant the device exists at any time. The physician may elect to discontinue the use of the Sentio system at any time in favour of alternative medical devices. Explanation or re-implantation according to the manufacturer*s instructions is not expected to cause damage of the residual hearing or any other risks other than the general risks associated with surgery.

There is a moderate risk for some adverse device effects for the study participants. These adverse device effects may include for example:

•Temporary pain or discomfort during use due to the pressure from the magnetic retention system, normally resolved by adjustment of the magnet strength.
•The implant and sound processor contain magnets. Pain and discomfort can occur during/after MRI. Active implantable devices (e.g. magnetic shunts) could be influenced by the internal or external magnets, causing failed treatment of other medical condition.
•There are general risks associated with surgery that could occur (improbable risks) which could result in, e.g. complications from anaesthesia, infections, bleeding, blood clots, numbness and pain. During and after implant surgery in the scull there are also (improbable) risks that could result in e.g. facial paralysis, infection/intracranial complications, periimplantitis.

Potential benefits include improved ability to hear sounds and improved speech intelligibility. In addition, the Sentio system is expected to provide improved quality of life and reduce the disability caused by a hearing loss for patients within the intended use.

Overall, the residual risks associated with the use of the Sentio system are of low severity and comparable to similar products on the market when the system is used as intended.

Furthermore, it is concluded that the anticipated risks associated with participation in the investigation are acceptable when weighted against the

anticipated user benefits of participation.

MRI sub-study:
The Sentio Ti implant is expected to lead to no or minimal discomfort during the MRI scan and the MRI scan will be conducted in accordance with the MRI safety guidelines for the Sentio system. The MRI safety was confirmed by extensive testing according to applicable standards. The inclusion and exclusion criteria have been set to avoid inclusion of any participant who may not be suitable to undergo an MRI examination. Participants volunteering to the sub-study will continue to attend the follow-up visits scheduled as part of the main clinical investigation. As no patient has yet undergone an MRI with the Sentio Ti implant in situ, the risk assessment has been based on comprehensive pre-clinical testing according to applicable standards and existing literature. When compared to the generated knowledge and potential benefit for future patients, it is concluded that the risks
associated with the sub-study are acceptable in the context of the clinical investigation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1.Signed Informed Consent Form
2.Adult subjects (18 years or older)
3.Subjects with
3.1.conductive or mixed hearing losses with pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2 and 3 kHz) of the indicated ear better than or equal to 45 dB HL.
3.2.OR subjects who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e. SSD). The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should then be better than or equal to 20 dB HL (measured at 0.5, 1, 2 and 3 kHz)
3.3.OR subjects who are indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.
4.Fluent in local language
5.Subjects who have the ability and are willing to follow investigational procedures/requirements, e.g. to complete quality of life scales.

MRI sub-study
- Enrolled in the BC101 clinical investigation.
- Signed informed consent for the MRI sub-study.
- Minimum 6 weeks post-surgery.

Exclusion criteria

1.Inability to undergo general or local anaesthesia
2.Prior implantation with percutaneous device or middle ear implant on the side to be implanted
3.Known medical conditions that contraindicate undergoing surgery as judged by the investigator
4.Untreated ongoing middle ear infection at the time of surgery
5.Known insufficient bone quality/quantity/depth or skull size (scull abnormalities) for implantation of a Sentio Ti Implant
6.Known or suspected contact allergy to silicone or other material used in the Sentio system.
7.Known condition that could jeopardize wound healing and skin condition e.g. uncontrolled diabetes over time as judged by the investigator.

8.Known skin or scalp conditions that may preclude attachment or interfere with the usage of the SP.
9.Known retro cochlear pathology and auditory processing disorders that may have an impact on the outcome of the investigation
10.Any other known condition that the investigator determines could interfere with compliance or investigation assessments.
11.Use of ototoxic drugs that could be harmful to the hearing, as judged by the investigator.
12.Subject that has received radiotherapy in the area of implantation or is planned for such radiotherapy or similar during the investigation period.
13.For bilateral asymmetric candidates, subject already treated with a bone-anchored hearing solution on the side with the best BC thresholds
14.Known chronic or non-revisable vestibular or balance disorder
15.Known abnormally progressive hearing loss
16.For conductive and mixed losses: evidence that hearing loss is retro-cochlear or central origin
17.Participation in another clinical investigation with pharmaceutical and/or device which might cause interference with investigation participation.
18.Use of active implantable or body worn device that for medical reasons cannot be removed or discontinued, such as CSF shunts, implantable cardiac pacemakers, defibrillators, or neurostimulators.
19.Known need for frequent MRI investigations for follow-up of other diseases.
20.Any subject that according to the Declaration of Helsinki is deemed unsuitable for investigation enrolment.

MRI sub-studie:
- Use of other implantable or bodily worn devices that cannot be removed or are not MRI safe under the conditions of the MRI scan done in this sub-study.
- Unsuitable for MRI examination for any reason, judged by the investigator and/or the radiology staff.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-01-2022
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Sentio System
Registration:	No

Ethics review

Approved WMO Date:	08-12-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-07-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-12-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-02-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL77672.000.21