Stability, long term survival and tolerability of a novel Baha® implant system, a multi-centre investigation.

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Primary Objective: To show superiority of the novel fixtures compared to standard fixtures regarding stability of the implants measured as ISQ values.Secondary Objectives: 1. To compare the long time survival of the standard fixtures and abutments...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hearing disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31607

Source
ToetsingOnline

Brief title
Long term evaluation of a novel baha fixture and abutment.

Condition

- Hearing disorders
- Skin and subcutaneous tissue disorders NEC

Synonym
implant stability, local skin reactions

Research involving
Human

Sponsors and support

Primary sponsor: Cochlear BAS
Source(s) of monetary or material Support: Cochlear Bone Anchored Solution;Sweden.

Intervention

Keyword: Baha, Baha abutment, Baha fixture, long term evaluation

Outcome measures

Primary outcome

Primary efficacy variables

RFA measurements will be done from time 0, visit 1, and onwards. The RFA measurements will be done with the abutment in place. The Smartpeg will be fastened to the abutment with a torque wrench standardising the momentum to 10 Ncm. The measurement will then be done. The RFA measurement results in ISQ values reflecting the stability of the fixture. The ISQ values will be recorded in three directions parallel to the skull; one horizontal from the front pointing backwards, two vertical; from above pointing down and one from below pointing upwards (see Appendix 5 for Instructions for use of the RFA equipment). Each ISQ recording may provide one or two values. Two values will result if the equipment detects differences in the ISQ value in its analysis of the fixture stability between two directions and thus cannot present just one value. In these instances will both values be recorded. The ISQ value ranges from 1 to 100. A higher value reflects a more stable fixture.

Secondary outcome

Secondary efficacy variables

Loss of the implant will be recorded from visit 2, day 10, onwards. Loss of the implant is defined as actual loss of the implant from the site of implantation. If this occurs between planned visits to the clinic patients will be encouraged to contact the clinic to record the event, but also to receive treatment

according to the clinical routine, and to be withdrawn from the study. Loss of the Implant / fixture is a study end point.

Local reactions like infection may lead to the explantation of the fixture. This is also defined as a study end point and will be recorded accordingly. The number of patients at each visit with implant survival will be reported. Data from visits in-between planned visits will be captured on the extra CRF pages provided. Loading of the Baha sound processor at 6 weeks post implant will be recorded using the ISQ values.

Study description

Background summary

The Baha® system is an implant for patients with typical conductive or mixed (conductive and sensoneural) hearing loss. In principle; a titanium fixture, which is integrated with the bone tissue of the skull, is connected to an external vibrating unit via a skin penetrating abutment. The vibrator is transforming sound into vibrations, which is conducted via the titanium fixture to the skull and onwards to the hearing organ, the cochlea.
Today, the fixture is a standard Brånemark type of implant, which initially was developed by Nobel Pharma AB, which later became Entific medical systems AB and was bought by Cochlear Ltd. There is a clear connection to dental implants although, the Baha® system are subjected to less stress and must use much shorter fixtures (typically 4 mm long).

As there has been substantial development of titanium fixtures for the dental industry, there are good reasons for improving the Baha® implant system.
The standard Baha® implant is a class IIb medical device and the new modifications will not change the classification.
There are mainly two modifications to the new implant system. First, a change of design, which distributes the load on the bone better.
The second modification is the surface topography of the fixture. A modification resulting in a moderately rough surface is achieved. The modification method used has been used with excellent clinical results in dental practice for more than 10 years. There is no reason to believe that the fixture in the Baha® application should react adverse to that.
An improved fixture can allow earlier loading. Today, 12 weeks are recommended

to achieve good osseointegration. In clinical routine care a shorter period then the 12 weeks are often used though. With the new system the 12 week period can probably be significantly shortened. The novel fixture will most likely have a better stability and an improved long-term survival.
The new Baha® implant system is to all knowledge and considerations an improvement without any increased patient risk. To fully evaluate the new system, a randomized clinical trial will be done.

Study objective

Primary Objective:
To show superiority of the novel fixtures compared to standard fixtures regarding stability of the implants measured as ISQ values.

Secondary Objectives:
1. To compare the long time survival of the standard fixtures and abutments with the novel fixtures and abutments in the Baha system.
2. To compare safety of the standard fixtures with the novel fixtures measured as local reactions and Adverse Events and Adverse Device Effects. These events will be recorded as local reactions at the implant site and any adverse events.
3. To support loading of Baha sound processor at 6 weeks post implant.

Study design

The bone anchored hearing implant (Baha®) has been used clinically for about 30 years and some 35.000 patients have been fitted with the system. The Baha® is a hearing implant used for patients with conductive, sensorineural or mixed hearing loss.

A central issue to bone anchored hearing implants (Baha®) is that the titanium fixture is properly integrated with the skull bone. This integration is often referred to as osseointegration where outermost titanium dioxide (TiO2) layer is biochemically bonded to calcium phosphate of the bone.

Similar to the advancements in dental implant technology, there are some improvements that can be incorporated in the Baha® implant system. The two main improvements we are focusing on is A) a design with better load bearing properties and B) a surface topography of the fixture with better osseointegrating abilities. The suggested modifications will, according to state of the art science as well as clinical experience, improve the success rate for the patients and introduce an option for earlier loading of the sound processor.

The hypothesis is that there is a difference in stability between the novel implant and the standard/control implant. The implant stability is measured by a Resonance Frequency Analysis.

The novel implants and the standard/control implants will be randomised in blocks of 3 in the proportions 2:1.

The patient must meet the following criteria to be included; adult patients, i.e. >=18 years, written informed consent, eligible for the Baha system, bone thickness at the implant site of at least 4 mm, eligible for implantation with the two fixtures; 3,75 alternatively 4,5 mm wide, no known disease or treatment that compromises / will compromise the bone quality at the implant site.

The investigation is designed as an open, multi-centre, randomised, comparative, prospective long term investigation.
The timetable for the study will be 10 patient follow-up visits 10 days, 4, 6, 8, 12 weeks and 6, 12, 24 and 36 months after fixture insertion.The total study time will be 3,5 year including patient enrollment period.

The comparator is a standard 4,0 mm titanium fixture and abutment in the Baha system.
Test Product: The test product is the novel fixture and abutment for the Baha system developed by Cochlear BAS AB.
In the study 72 patients will be enrolled at 4 clinics. The aim will be 66 evaluable patients.

The insertion of the novel fixture will essentially be similar to the conventional Baha fixture insertion.
The test device (fixture and abutment pre-mounted) will be inserted with the abutment inserter. In case of need for abutment removal, a counter torque wrench is used together with standard screwdriver unigrip 95mm.
Since the new fixture is slightly wider, a wider hole must be drilled using accompanying drill set.
A healing cap with new dimensions will be used during the healing period.
RFA measurements will be done from time 0, visit 1, and onwards. The RFA measurements will be done with the abutment in place.

Risks involved in this study are related to the novel design of the fixture and abutment that 2 of 3 patients will receive. The standard system is known to be well tolerated and to have a good survival rate; 94%. The novel design changes are not expected to be less well tolerated then the standard design of the fixture and the abutment. The titanium surface used for the novel fixture and abutment is a well known surface for dental applications, it has a slightly modified topography compared with the standard fixture and abutment. Therefore, it is not foreseen that the novel design will increase the risk for the patient relative to the standard system. The new Baha implant system is to all knowledge and considerations an improvement without any increased patient risk. Follow up is done regularly and in the case of untoward events the patients are encouraged to contact the clinic. The patients will be provided with contact details.

The novel fixture and implant have been developed to provide a fixture and abutment that performs better over time, i.e. has greater stability, less reactions locally and has a higher survival rate. If this is the case then this will be a benefit for the 2 thirds of the patients allocated to the novel system. The study will have regular and more standardised follow-up then conventional care. Otherwise there will be no treatment benefits for the patients.

An interimanalysis is planned after 6 months.
Feedback of research results will be communicated to the participants and other interested persons in a coprehensible way.

I the patient information leaflet all necessary information to the participants will be presented, included risks and study plan.
The participant will give a written consent and will keep copies of both the information sheet and the consent.

Study burden and risks

The novel design changes are not expected to be less well tolerated then the standard design of the fixture and the abutment. The titanium surface used for the novel fixture and abutment is a well known surface, which has a slightly modified topology compared with the standard fixture and abutment. Therefore, it is not foreseen that the novel design will increase the risk for the patient relative to the standard system.

The most likely risk is that an infection could occur in the interface between the skin and the implant. Very rarely such infections lead to implant loss. Most often these infections are successfully treated.
During the study follow-up period this and other possible adverse effects will be investigated carefully. The patients are encouraged to contact the investigator if any problems occur in between the planned visits.
The study follows the standard procedures for a Baha implantation.

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

The patient must meet the following criteria to be included;
• Adult patients, i.e. >=18 years
• Written informed consent
• Eligible for the Baha system
• Bone thickness at the implant site of at least 4 mm
• Eligible for implantation with the two fixtures; 3,75 alternatively 4,5 mm wide
• No known disease or treatment that compromises / will compromise the bone quality at the implant site

Exclusion criteria

The patient should meet none of the following criteria
• Unable to follow investigational procedures
• Simultaneous participation in another investigation with pharmaceuticals and/or devices
• Any factor, at the discretion of the investigator that is considered to contraindicate participation.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-03-2009
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	19-01-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL20489.091.08