The Baha Microbiome Case Control Study - A Molecular Bacterial Profile Of The Baha

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38635

Source
ToetsingOnline

Brief title
BMCCS1

Condition

- Other condition
- External ear disorders (excl congenital)
- Bacterial infectious disorders

Synonym
implant inflammation, Peri-implant dermatitis

Health condition

Peri-implant dermatitis

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Cochlear Bone Anchored Solutions,door industrie: Cochlear Bone Anchored Solutions

Intervention

Keyword: Baha, IS-PRO, microbiome, microbiota

Outcome measures

Primary outcome

The main study parameter is the molecular bacterial profile of the Baha

abutment as expressed in IS-lengths and quantities.

Secondary outcome

Secondary study parameters are the correlations between bacterial flora and

the change in flora in relation to clinical peri-implant skin infections.

Study description

Background summary

The Bone-Anchored Hearing Aid (Baha) system consists of an implanted part and sound processor. The system provides a hearing solution for a subgroup of patients who cannot sufficiently profit from conventional hearing aids. Disadvantageous are its high rate (up to 40%2,3) of associated peri-implant dermatitis. This research project is part of an attempt to reduce the amount of peri-implant dermatitis. Besides an attempt of Holgers to identify the skin flora in relation to infection around the abutment using a standard culture which yielded limited and no clinically relevant results, little is known about the microbiome on the abutment or its interaction with the commensal skin flora. Moreover, conventional cultures are not very sensitive in identifying bacteria. In 2010, Budding et al. introduced IS-pro. Is-pro is a novel 16S-23S rDNA interspace (IS)-region-based profiling method. This technology was devised to enable high-throughput molecular fingerprinting of microbioma. Since IS-pro is quick and relatively inexpensive, these environments can also be monitored

over time by repeating the test. This paves the way for researching the microbiome on the abutment and it could enable clinically objective follow up of treatments in vivo using the human as a host. This technique allows researchers to even discover unknown, previously unidentified bacteria. Additionally, Scanning Electron Microscopy will be used to assess the spatial distribution and composition of bacteria on the abutment. The first step, using these techniques, is to determine the bacteria which inhabit the abutment also in relation to the surrounding skin. Additionally, the relationship with skin-implant infections and the effect of treatments will be monitored. Depending on these primary scientific results, a subsequent study will be devised to study (experimental) treatments in a randomized, controlled fashion.

Study objective

The primary objective of the study is to identify the bacterial flora on the abutment in a phylum/species classification. The secondary objectives are to assess the relationships between the commensal skin flora and the flora on the abutment and to study if clinical signs of peri-implant skin infection and subsequent treatment are associated with a change in bacterial composition. The tertiary objective is to assess if there exists a relationship between skin hygiene and the transient skin flora.

Study design

The study will be performed in a single tertriary center. The investigation has an observational, case-control design in which the abutment will be replaced for further analysis. The inclusion period is 12 months.

Intervention

A baha abutment switch.

Study burden and risks

In general, the risk in participating in this research will be low. The burden for patients will mainly consist of having a several swabs collected which will only take a few minutes. The abutment switch can sometimes be uncomfortable or in the worst case painful. The patient could hear the unscrewing process. In theory there could be a slight increase in the risk on peri-implant dermatitis. Also, if there exists a loss of Osseointegration (a complication on its own), the abutment change should be aborted to prevent the removal of the implant. In case inflammation arises, this can be handled with antibiotic ointments. Overall, there will be no direct benefit for the individual patient. But the increase in knowledge can be of added value to the current and future Baha patient group.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet the following criteria
1. The patient is at least 18 years old
2. The patient has a Cochlear Baha.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study if there exists:
1. Participation in the Cochlear CBAS5439 study.
2. The new abutment is not compatible with the current and future hearing aid.
3. Patients can be included until both arms (controls vs. cases) are filled up.

4. A condition that may have an impact on the outcome of the investigation as judged by the investigator (e.g. severe wound healing impairments). If so the reason should be noted. In general, patients who potentially could have severe wound healing impairments based on their medical history are excluded. This would include:
a. Unregulated Diabetes Mellitus (DM). This is based on an prolonged elevated HbA1c (for more than 3 months > 7%) or patients reporting to have difficulties regulating their glucose and/or the presence of infectious diseases related to DM.
b. Any systemic immunosuppressant usage (e.g. corticosteroids).
c. The usage of topical or systemic antibiotics which could affect the skin (e.g. excludes systemic antibiotics for urinary tract infections).
d. Skin diseases (e.g. cases of psoriasis, eczema or other skin diseases which have in the past or currently involved the skin on the head, have a tendency to arise on disrupted skin or are not well predictable in their location and recurrence).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-04-2014
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Replacement of the Baha abutment
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-11-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL42957.068.13

Study results

Date completed:	28-09-2016
Actual enrolment:	16

Summary results
Trial is onging in other countries