Minimally invasive surgery for Ponto bone anchored hearing implants

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Primairy objective:To compare the incidence of inflammation between the test group (MIPS technique using an Oticon Medical Ponto abutment and implant) and control group (Hultcrantz technique using an Oticon Medical Ponto abutment and implant) after...

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

Summary

ID

NL-OMON44599

Source
ToetsingOnline

Brief title
C50

Condition

- Hearing disorders

Synonym
deafness, hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Oticon Medical AB
Source(s) of monetary or material Support: Oticon Medical

Intervention

Keyword: Bone Anchored Hearing Aids, Complications, Minimally invasive surgery, Oticon Ponto

Outcome measures

Primary outcome

The primary endpoint will be the incidence of inflammation. Incidence of

inflammation is calculated as the sum of patients with one or more observations

of Holgers index of 2 or higher between surgery and 3 months post-surgery.

Secondary outcome

After 3 months post-surgery

- Presence of dehiscence after surgery

- VAS pain scale >6

- Loss of sensibility

- Soft tissue overgrowth

- Extrusion rate

- ISQ measurments

- Skin position

- Dynamic skin motion

- Surgical time

- Wound healing time

After 24 months post-surgery

- Holgers index of two or higher at any timepoint

- Presence of dehiscence after surgery

- VAS pain scale >6

- Loss of sensibility

- Soft tissue overgrowth

- Extrusion rate

- ISQ measuremnts

- Cosmetic result

Study description

Background summary

1 Clinical experience with Ponto
Bone conduction implants (BCI) such as the Ponto® system were first clinically described in 1977 by Tjellström et al., and since then more than 120.000 patients have been treated with this technique. The Ponto system consists of a titanium implant, which is integrated with the bone tissue of the skull and is connected to an external sound processor via a skin penetrating abutment. The sound processor transforms sound to vibrations that are transmitted via the abutment and titanium implant to the skull bone and then to the cochlea. This provides hearing amplification for patients who experience profound hearing loss for various reasons and who are unable to benefit from a conventional hearing aid.
2 The surgical procedure
There are a few different surgical techniques to implant the Ponto system. The common technique used today is to make an incision next to the implant-position and prepare the right position for the implant from this opening for the Ponto system. With a *punch* through the skin above the implant-site to expose the abutment. The original incision will be closed using sutures. With the new operationtechnique the entire procedure will be done through the punch opening. Therefore making the original incision obsolete.

Study objective

Primairy objective:
To compare the incidence of inflammation between the test group (MIPS technique using an Oticon Medical Ponto abutment and implant) and control group (Hultcrantz technique using an Oticon Medical Ponto abutment and implant) after 3 months post-surgery

Secundairy objectives
To compare performance indicators between the MIPS technique and Hultcrantz technique
- Presence of dehiscence after surgery
- Pain
- Loss of sensibility
- Soft tissue overgrowth
- Extrusion
- Surgical procedure time
- Wound healing
- ISQ values

To evaluete it the skin position and movement of the skin around the abutment are affected by the surgical technique (MIPS technique and Hultcrantz technique)

Tertiary objectives:
- To validate the Holgers index
- To assess the correlation between the Holgers index and biological markers such as cytokines and the bacterial profile on the abutment, in and on the skin
- To collect data for a full economic evaluation
- To develop a peri-implant dermatitis scale and compare it to the Holgers index.
- To compare the quality of lift after surgery between the MIPS techniqe and the Hultcrantz technique

Study design

An national single center, open, randomised, comparative, parallel group, prospective clinical investigation. 1 year investigation with a 2 year follow-up

Intervention

The surgical placement (conventional versus the investigational surgical technique) of the Ponto-system

Study burden and risks

1. Burden
The extra burden for patients in participating in this study is minimal and consists mainly out of the completion of multiple questionnaires and an investment of time over a period of 3 years. 3 months after the operation we will collect a small tissue sample from the region around the abutment. This will take place on a regular control-moment using a micro-biopsy punch and the burden is comparable with a regular vena punction.

2. Risks
There are no foreseeable additional risks (when compared to the conventional Ponto procedure) for patients in participating in this study. Bone anchored hearing devices have been implanted for over 35 years now. The simplified surgical technique is already being put to practice in several clinics around the world and clinical studies have deemed it safe. The product has been certified with a CE marking. The risks of the micro biopsy punch are comparable with a venapunction. Namely, a bleeding, hematoma, local pain and local redness.

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

• Adult patient, i.e. >= 18 years of age

• Eligible for the Ponto system
• Signed informed consent

Exclusion criteria

A potential subject who meets the inclusion criteria for Ponto surgery, is willing to participate in the trial and meets any of the following criteria will be excluded from participation in this study.
- Known history of immunosuppressive disease
- Use of systemic immunosuppressive medication
- Receiving bilateral bone anchored hearing system
- Relevant dermatological diseases as judged by the investigator
- Not being able to finish the study, for example because of failure to complete the questionnaires
- Participating in another study with medical aids or medication
- When there is no suitable implantation-site for the 4 mm implant during surgery because of insufficient bone quality.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2014
Enrollment:	62
Type:	Actual

Ethics review

Approved WMO Date:	24-11-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-06-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-09-2015
Application type:	Amendment
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	NL50072.068.14