Single-stage bone-anchored hearing implant surgery in the pediatric population using the BHX implant

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To compare implant loss between single-stage BAHI surgery (test group) and two-stage BAHI surgery (control group) in children. Furthermore, to compare soft tissue status, time to loading and duration of surgery between groups.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Ear and labyrinthine disorders congenital
Study type	Interventional

Summary

ID

NL-OMON48180

Source
ToetsingOnline

Brief title
Single-stage surgery using the BHX implant

Condition

- Ear and labyrinthine disorders congenital
- Middle ear disorders (excl congenital)
- Head and neck therapeutic procedures

Synonym
conductive hearing loss, hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

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

Intervention

Keyword: BCD, Children, Implant loss, Single-stage

Outcome measures

Primary outcome

The main study parameter is the difference in implant loss between test and control group.

Secondary outcome

Secondary study parameters are the differences in implantstability, soft tissue status, time to loading and duration of surgery between groups. Total follow-up after surgery will be one year.

Study description

Background summary

Over the last few decades, the classical two-stage surgical procedure has been modified in adults into a single-stage procedure. This approach has several advantages since it avoids a second surgical procedure. The single-stage approach is proven to be safe and feasible in adults and is nowadays referred to as the standard surgical technique in adults. A few centers already implemented this technique for children and show a low rate of early complications and fixture loss due to osseointegration failure, suggesting that single-stage surgery in children might be feasible. Despite these favorable outcomes and advantages of the single-stage surgery, most ENT-surgeons still perform two-stage surgery when inserting BAHI in the pediatric population. This is due to the limited number of prospective comparative studies and the fear for implant loss in a vulnerable population. In previous studies, reported implant loss rates were twice as high in children compared to adults. However, after the introduction of the wide diameter implants, short- and long-term implant loss rates declined in adults. Therefore, we believe it is safe to initiate single-stage surgery in the pediatric population. Reliable evidence which proves the safety of the single-stage procedure should be provided in

order to implement this surgery as the regular care in children.

Study objective

To compare implant loss between single-stage BAHI surgery (test group) and two-stage BAHI surgery (control group) in children. Furthermore, to compare soft tissue status, time to loading and duration of surgery between groups.

Study design

Prospective comparative study with historical control group.

Intervention

In the test group, BAHI insertion will be performed using single-stage surgery. Patients in the control group already underwent BAHI insertion using two-stage surgery.

Study burden and risks

The number of site visits does not differ from the standard of care. In comparison to two-stage surgery, single-stage surgery avoids a second general anaesthesia, reduces operation time and allows for earlier hearing rehabilitation. So far, only a few centers already implemented the single-stage surgery in children and showed a low rate of early complications and fixture loss due to osseointegration failure. However, most studies evaluating single-stage surgery in children are retrospective studies with a small sample size and vary in surgical technique, age range and follow-up duration. There is a minimal risk that single-stage surgery will lead to an increase in implant loss due to failure of osseointegration, resulting in the need for a second surgery. However, this makes no difference since a second surgery would also be performed in case of the standard two-stage procedure.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Test group
- Age 4-9 years
- Indication for percutaneous bone-anchored hearing implant surgery with a BHX implant
- Insertion using the linear incision techniqueControl group (historical)
- Children who underwent implantation of a wide diameter implant using two-stage surgery between 2012 and 2018 at the Radboudumc
- Age 4-9 at the time of surgery

Exclusion criteria

Test group
1. Inability to show up at all follow-up visits
2. Patients undergoing re-implantation
3. Diseases, syndromes or treatments known to compromise the bone quality at the implant site, e.g. radiotherapy, osteoporosis, diabetes mellitus.
4. Insufficient bone thickness <=1mm, since conversion to two-stage surgery will be advocatedControl group
1. Follow-up duration less than 1 year.
2. Diseases, syndromes or treatments known to compromise the bone quality at the implant site, e.g. radiotherapy, osteoporosis, diabetes mellitus (at moment of implantation)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-09-2019
Enrollment:	22
Type:	Actual

Ethics review

Approved WMO Date:	01-08-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-09-2019
Application type:	Amendment
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
ClinicalTrials.gov	NCT04039802
CCMO	NL69973.091.19