Translabyrinthine acquisition of human adult cochlear tissue for molecular and cellular characterisation of the human cochlea

Published: 05-01-2023
Last updated: 07-06-2025

To study the human adult cochlea, in specific it's RNA and protein expression patterns and morphology.

Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Observational invasive

Summary

ID

NL-OMON53687

Source
ToetsingOnline

Brief title
Molecular and cellular characterisation of the human cochlea

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
1. Normal inner ear. 2. Deafness

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Eerste geldstroom (geld van Ministerie van

OC&W aan universiteiten)

Intervention

- Surigical procedure

Keyword: cochlea, inner ear, otobiology

Explanation

N.a.

Outcome measures

Primary outcome

RNA and protein expression profiles and morphology analysis of the human cochlea compared to inner ear organoids.

Secondary outcome

N/A

Study description

Background summary

Pathologies of the inner ear are among the most significant global health problems and costs. Relatively little is known about these diseases, mainly due to the limited access to this organ (which makes it very difficult to study). Apart from technical devices such as hearing aids and cochlear implants, there are no real therapeutic options yet.

It is essential to increase our knowledge about the human cochlea: its anatomy, development, pathologies, and gene and protein expression profiles. Additionally, there has recently been a development in generating inner ear organoids from human-induced pluripotent stem cells. To compare this promising cellular model with their real adult human counterpart, it is also necessary to acquire adult cochlear human tissue. Providing more knowledge about the human adult cochlea will benefit both researchers and physicians worldwide.

Study objective

To study the human adult cochlea, in specific it's RNA and protein expression patterns and morphology.

Study design

Fundamental research

Intervention

Additional acquisition of cochlear tissue.

Study burden and risks

Included patients will undergo a translabyrinthine surgery, because of standard medical care reasons (usually this is a vestibular schwannoma). This is a major surgical intervention with a long duration (all day surgery) and
various significant risks (such as facial nerve paralysis, intercranial haemorrhage, brain infection, liquorrhea). During and due to this intervention patients will completely lose their remaining inner ear function (both cochlea and vestibular system). However, the cochlear tissue will normally stay inside the patient (even though with complete loss of function). To also access the cochlea, the surgeon has to open up the inner ear a few millimeters outside of the standard (translabyrinthine) surgical route. This is an extremely limited
extension of the entire translabyrinthine procedure. The only postoperative difference for the included patients is that they will have an additional ear tampon underneath their head bandage. In light of the translabyrinthine
approach and involved risks, there are no increased or additional risks for the patient during this extended procedure.

Contacts

Scientific
Leids Universitair Medisch Centrum
H Locher
Albinusdreef 2
Leiden 2333ZA
Netherlands
0715262434
Public
Leids Universitair Medisch Centrum
H Locher
Albinusdreef 2
Leiden 2333ZA
Netherlands
0715262434

Trial sites

Trial sites in the Netherlands

Leids Universitair Medisch Centrum
Target size: 20

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- A planned translabyrinthine approach, part of standard medical care
- Preoperative good or residual hearing at the affected side
- Age 18 years and over, who have mastered the Dutch or English language

Exclusion criteria

Mentally incapacitated

Study design

Design

Study phase:	N/A
Study type:	Observational invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	09-02-2024
Enrollment:	20
Duration:	1 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Yes

Plan description
Geanonimiseerde data zullen na publicatie gedeeld worden op nader te bepalen online repositories.

Ethics review

Approved WMO

Date:	16-02-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	25-03-2025
Application type:	Amendment
Review commission:	METC LDD

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	NL82900.058.23
Research portal	NL-006988