Vestibular function in the follow-up of patients with Vestibular Schwannoma (FUVES)

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To evaluate the vestibular function relating results to surgery, radiotherapy, active surveillance, intratympanic gentamicin, and intratympanic gentamicin followed by active treatment based on objective vestibular testing and dizziness related QoL...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON52093

Source
ToetsingOnline

Brief title
Evaluation of vestibular function in patients with Vestibular Schwannoma

Condition

- Other condition
- Inner ear and VIIIth cranial nerve disorders

Synonym
vestibular schwannoma - acoustic neuroma

Health condition

vestibular function

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Vestibular assessment, Vestibular function, Vestibular Schwannoma

Outcome measures

Primary outcome

The changes in objective vestibular test results and dizziness related QoL

during follow-up.

Secondary outcome

• To correlate the pre-operative vestibular function with the post-operative

patient vestibular disability and handicap.

• To correlate the irradiation dose-volume to the vestibular organs with

vestibulo-toxicity after radiotherapy.

• To correlate the natural development of the vestibular function over time in

active surveillance.

• To determine the effect of ITG in the vestibular function and vestibular

complaints, with objective and subjective vestibular tests.

• To correlate the questionnaires (DHI, PANQOL and SF-36) results with

vestibular function.

Study description

Background summary

Vestibular schwannoma (VS) is a rare, benign tumour arising from the Schwann

cells of the vestibular nerve. It is commonly associated with tinnitus and sensorineural hearing loss. Moreover, it is a tumour that grows in the vestibular nerve and thus has the ability to affect the vestibular function. The majority of patients with a vestibular schwannoma will present with asymmetric hearing loss and/or vestibular complaints such as balance disturbance or vertigo. It has been demonstrated that the vestibular symptoms have a major impact on the quality of life of vestibular schwannoma patients. It is therefore of paramount clinical importance to evaluate vestibular function in this patient group and gain insight into the progression of these symptoms over time, in relation to the vestibular schwannoma management strategy.
Up to now, no prospective study has been performed evaluating vestibular function in VS patients. The current study will focus on vestibular function in relation to vestibular schwannoma management strategies: surgery, radiotherapy, active surveillance (wait and scan policy), or intratympanic gentamicin followed by active treatment (surgery or radiotherapy). The variables that will be studied include dizziness, vertigo, hearing loss, cognitive-psychological function. The primary aim is to evaluate vestibular function and vestibular compensation processes over time and in relation to treatment strategy and patient characteristics.

Study objective

To evaluate the vestibular function relating results to surgery, radiotherapy, active surveillance, intratympanic gentamicin, and intratympanic gentamicin followed by active treatment based on objective vestibular testing and dizziness related QoL.

Study design

Prospective observational single-center cohort study.

Study burden and risks

The VS patients will be subjected to standard clinical care and diagnostics, with the exception of objectibe vestibular function assessments.

The vestibular tests used in this study are well-established, not experimental in themselves, and do not represent risk for the patient. We consider the risk of participating in this study to be negligible.

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

• aged 18 years or older
• being diagnosed with unilateral vestibular schwannoma
• with or without active VS treatment indication (i.e. RT, S or AS)
• with or without severe vestibular signs or symptoms
• able to provide a written informed consent

Exclusion criteria

• active additional neuro- otologic disorders
• severe disability (e.g. neurological, cardiovascular, orthopedic, psychiatric) or
• serious concurrent illness that might interfere with vestibular evaluation
• patients under medical treatment that affects the vestibular function

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-03-2021
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO

Date:	08-12-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	30-05-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27070
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL74697.058.20
Other	NL9176
OMON	NL-OMON27070