Prospective Evaluation of Vestibular Schwannoma Irradiation

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Primary Objectives: • To evaluate the subjective and objective cognitive complaints and cognitive function in patients receiving radiotherapy for their vestibular schwannoma. Secondary objectives:• To explore the use of (MRI) imaging biomarkers for…

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

Summary

ID

NL-OMON54239

Source
ToetsingOnline

Brief title
PEVI

Condition

- Inner ear and VIIIth cranial nerve disorders
- Nervous system neoplasms benign

Synonym
acoustic neuroma, vestibular schwannoma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: This study is partly funded by 1) the Surcharge for Top Consortia for Knowledge and Innovation (TKIs) from the Ministry of Economic Affairs and Climate.,Varian Medical Systems

Intervention

Keyword: Cognition, Hearing loss, Imaging, Radiotherapy, Vestibular schwannoma

Outcome measures

Primary outcome

• A decreased cognitive performance, defined as more than 1 standard deviation

difference from reference groups.

• cognitive change during follow-up.

Secondary outcome

• Hearing and vestibular assessments.

• (Health-Related) Quality of Life and mood status.

• Radiological biomarkers/(f)MRI changes during follow-up.

• Validation of two adjusted cognitive tests.

Study description

Background summary

Vestibular schwannomas (VS) are benign nerve sheath tumors arising in the cerebellopontine angle, in between the petrous bone and the brainstem. Early symptoms comprise hearing loss, dizziness and/or unsteadiness and tinnitus. Most people are initially managed with an active surveillance protocol, comprising control for tumor growth through regular MRI-scans. Large or growing tumors are treated by radiotherapy or a surgical resection, with tumor control rates between 90-100%. Because patients have a normal life expectancy with timely intervention, maintaining functions and quality of life are of paramount importance in vestibular schwannoma treatment.
This study will look at the prevalence and longitudinal changes of hearing loss and objective and subjective cognitive problems in patients undergoing treatment with radiotherapy for vestibular schwannoma. Cognitive functioning is a complex and dynamic system. In vestibular schwannoma patients it could be affected in multiple ways: by the tumor causing pressure on adjacent (brain) structures, secondary to symptoms (as tinnitus, hearing/balance impairment, mood disorder), because of the treatment itself

(radiotherapy/surgery), and perhaps through other pathways still unknown. There is one previous study on cognitive testing prior to vestibular schwannoma surgery, which found multiple cognitive domains affected in their patient population.
Hearing loss has been associated with cognitive impairment, even when the hearing loss is subclinical. To maintain optimal understanding, listeners with hearing loss must allocate more cognitive resources to speech processing than listeners without hearing loss. Research further suggests that the sustained cognitive effort required to offset auditory degradation due to hearing loss may lead to subjective reports of mental fatigue. In addition to hearing loss, VS patients also experience tinnitus and balance problems. These symptoms may influence patients in a similar way as hearing loss does (by shifting more resources from other ongoing cognitive tasks and increasing fatigue). Mood disorders, such as anxiety and depression, also can have an effect on cognition and cognitive test results. For radiotherapy, there is growing evidence for cognitive alterations after brain irradiation. This can already occur at low radiation dosages (as described mainly in animal models). To better understand and/or predict the overall cognitive status and changes, possible MR imaging biomarkers are studied. For this study, the aim will be to qualitatively describe the difference in MRI brain function over time, and explore the correlation to treatment, symptomology, and subjective and objective cognitive functioning.

Study objective

Primary Objectives:
• To evaluate the subjective and objective cognitive complaints and cognitive function in patients receiving radiotherapy for their vestibular schwannoma.
Secondary objectives:
• To explore the use of (MRI) imaging biomarkers for cognitive and/or neuronal changes over time.
• To report treatment outcomes and radiation-induced toxicity (e.g. hearing deterioration, dizziness and/or unsteadiness) from a prospective observational cohort of vestibular schwannoma patients.
• To compare the group receiving radiotherapy to a control group without any active treatment for their vestibular schwannoma.
• To theoretically compare radiotherapy treatment plans of two different modalities (photon and proton radiotherapy) of the included patients.
• To compare and validate two adjusted cognitive tests (focused on balance and hearing) in vestibular schwannoma patients and healthy individuals.

Study design

Prospective, observational cohort study with invasive measurement.

Study burden and risks

The time of the additional diagnostics are the largest burden of this study. The risk is assessed as being low. The patient can have discomfort (claustrophobia, injection of contrast) or risk (allergy chance < 0,01%) from the MRIs.

Contacts

Public
Leids Universitair Medisch Centrum

albinusdreef 2
Leiden 2333ZA
NL
Scientific
Leids Universitair Medisch Centrum

albinusdreef 2
Leiden 2333ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- age of at least 18 years
- patient with vestibular schwannoma (radiologically proven diagnosis) with a radiotherapy treatment indication or active surveillance for control group A
- able to provide written informed consent, as determined by the treating physician
- ability to comply with the protocol, including cognitive testing and imaging

- written informed consent

Exclusion criteria

- previous surgical excision or radiotherapy for vestibular schwannoma
- incapacitated adults
- contra-indication for MRI
- impaired kidney function (eGFR known to be under 30 mm/min)
- Gadolinium allergy
- any prior cranial radiotherapy or chemotherapy
- any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule in the participating hospitals
- any serious medical condition that could interfere with follow-up
- severe aphasia, (functional) analphabetism or language barrier interfering with assessing endpoints
- pregnancy, lactation or intention to become pregnant during the study, since this is a contra-indication for undergoing Gadolinium-contrast enhanced MRI

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-04-2022
Enrollment:	145
Type:	Actual

Medical products/devices used

Generic name:	MRI
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-11-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	06-04-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	10-03-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-05-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	20-12-2024
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

No registrations found.

In other registers

Register	ID
CCMO	NL77901.058.21