

Evaluation of dizziness in patients with unilateral vestibular schwannoma (brughoehtumor)

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27070

Bron

NTR

Verkorte titel

FUVES

Aandoening

Unilateral vestibular schwannoma

Ondersteuning

Primaire sponsor: LUMC

Overige ondersteuning: LUMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The vestibular function relating results to surgery, radiotherapy and active surveillance based on objective vestibular testing and dizziness related QoL

Toelichting onderzoek

Achtergrond van het onderzoek

Currently the vestibular function is not well described in patients with unilateral vestibular schwannoma, nor is the effects of the different treatment modalities; surgery, radiotherapy or active surveillance. The vestibular symptoms such as dizziness, balance disturbance and/or vertigo are reported to have a major negative impact on the quality of life of the patients with vestibular schwannoma.

Hence, we aim to describe the vestibular function, function changes and dizziness related symptoms in vestibular schwannoma patients undergoing surgery, radiotherapy or active surveillance.

This study will increase our insight into the vestibular function and the impact of treatment strategy in this patient group. This in turn will help improve counselling of patients, enable adequate interventions if possible, and improve the quality of life of the patients with vestibular schwannoma.

Doel van het onderzoek

Vestibular schwannoma treatment have an impact on the vestibular function of vestibular schwannoma patients. Our hypothesis is that surgery and radiotherapy will impair at a certain point after treatment the vestibular function, while the active surveillance group will remain stable as long as the tumor size remains stable too.

Onderzoeksopzet

For the surgery group: before treatment, 5 to 7 days, 7 to 14 days, 1 month, 3 months, 6 to 12 months after surgery. For the radiotherapy group: before treatment, 6 weeks, 4 to 6 months, 1 year and 2 years after radiotherapy. For the active surveillance (wait and scan) group: baseline evaluation, 6 months, 12 months, 1 to 2 years.

Onderzoeksproduct en/of interventie

Surgery, radiotherapy and active surveillance (wait and scan)

Contactpersonen

Publiek

LUMC

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Aged 18 or older, being diagnosed with unilateral vestibular schwannoma, follow-up including either surgery, radiotherapy or active surveillance, able to provide a written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd

Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 07-01-2021
Aantal proefpersonen: 45
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 07-01-2021
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52093
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9176
CCMO	NL74697.058.20
OMON	NL-OMON52093

Resultaten