Perfusion MRI for vestibulair schwannoma, a growth predictor?

Published: 17-12-2012 Last updated: 30-04-2024

Optimalisation of the perfusion protocol for vestibular schwannoma.

Ethical review	Approved WMO
Status	Pending
Health condition type	Nervous system neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON35179

Source ToetsingOnline

Brief title Perfusion MRI for vestibular schwannoma

Condition

• Nervous system neoplasms benign

Synonym cerebellopontine angle tumors, vestibular schwannoma

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: growth, imaging, perfusion MRI, vestibular schwannoma

Outcome measures

Primary outcome

Quantification of perfusion.

Secondary outcome

not applicable

Study description

Background summary

Vestibular schwannoma remains difficult in decision making and timing of treatment. The difficulty lies in the unpredictable growth of these tumors, whether or not to decide for immediate treatment (operation or radiotherapy). Until now we judge tumors on their clinical and radiological features. The question is in which cases tumor growth is progressive and requires treatment. With the new perfusion MRI, vascularisation in tumors can be visualized. This technique has already been used in grading gliomas, prediction of early lung cancer and treatment reaction.

Perhaps this new imaging method is applicable for the vestibular schwannomas and the decision making is going to be easier in the future. First we perform a pilotstudy to measure the feasibility for a greater study.

Study objective

Optimalisation of the perfusion protocol for vestibular schwannoma.

Study design

Feasibility study

Growth: Growth is defined as, 4mm/yr or 20% volume expansion. Measured with MR imaging

Perfusion

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3 Tesla MR scan. Conventional MR axial plane, T1 weighted (TR/TE= 600/14ms),
T2 weighted (TR/TE= 5400/99 ms) and FLAIR imaging (TR/TE/TI = 9000/ 110/ 2100
ms). Perfusion is measured after first passage of gadolinium T2*W *PRESTO*
sequentie, using fast automatical (5ml/s) iv administration (0,2 mmol/kg).
First images are being used as the baseline.
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During the first passage of the contrast agent the T2* relaxation time and the T2* signal intensity decreases. The difference in relaxation time (*R2*) can be calculated with the formula $R2*(t) = \{-\ln(S(t)/S(0))\}/TE$. Where TE is the echo time, S(0) the baseline signal intensity and S(t) is the signal intensity at a particular time. R2* is depending on the quantity of the contrast agent within the lesion and the cerebral vlood volume (CBV) is the surface under R2* curve. With this data the relative CBV maps can be calculated and perfusion can be measured.

Study burden and risks

Risks are associated with vena puncture and contrast agent administration.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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Inclusion criteria

patients with a vestibular schwannoma with evident growth.

Exclusion criteria

small intracanaliculair vestibulair schwannoma

Study design

Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2012
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	perfusion MRI
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	17-12-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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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 CCMO **ID** NL38349.058.11