High-field MRI of the compression of the anterior visual pathway in pituitary adenoma

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Primary Objectives: - Assess the feasibility and clinical value of 7T MR to provide a more detailed anatomic description of the anterior visual pathway in NFMA patients compared to conventional MRI. - Assess the feasibility of high-field MRI to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON45804

Source
ToetsingOnline

Brief title
7T MR imaging of pituitary macro adenoma

Condition

- Hypothalamus and pituitary gland disorders
- Eye disorders NEC
- Head and neck therapeutic procedures

Synonym
macroadenoma, Pituitary tumour

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: Macroadenoma, MRI, Pituitary

Outcome measures

Primary outcome

Radiological descprition of the optic-chiasmatic system, this will lead to the

evaulation of:

-The configuration of the anterior optic pathway/optic chiasm

Ophthalmic description:

-Thickness of the optic-nerve fibre layer on OCT

-Visual field defect noted on Humphrey analyser

-Visual acuity through EDTRS-chart

-Visual functioning questionnaire

Secondary outcome

Not applicable

Study description

Background summary

Non Functional Macro-Adenomas (NFMA) are the most prevalent adenomas of the pituitary gland. Patients with a NFMA often present with compression on the anterior optic pathway sometimes combined with pituitary dysfunction. As a result of the mass effect, the tumour compresses the anterior optic pathway leading to visual field defects and sometimes decreased vision. Nowadays (endoscopic) trans-sphenoidal surgery is the first choice primary treatment. Surgical treatment is often successful in restoring most of the visual field defects but is less successful in restoring visual acuity. MR-imaging is

currently the main diagnostic tool, conventionally performed with a 1,5 or 3T (Tesla) MRI.

Study objective

Primary Objectives:

- Assess the feasibility and clinical value of 7T MR to provide a more detailed anatomic description of the anterior visual pathway in NFMA patients compared to conventional MRI.
- Assess the feasibility of high-field MRI to provide pathophysiological insight of poor visual function in NFMA patients after treatment

Secondary Objective(s):

- Assess the feasibility of high-field MRI to predict the effectiveness of treatment of NFMA.
- Assess for which of the primary objectives the increased resolution of the 7Tesla is needed or whether a conventional 3Tesla scan would be sufficient.

Study design

This study will be a single center, non-blinded study of subjects diagnosed with a pituitary adenoma. Patients will be scanned at different time points (pre treatment, 1 week post operatively, 6 months and 12 month time point) to assess the potential benefit of the 7T MRI over the 3T MRI for disease progression.

Initially the 7T MRI protocol will be validated to ensure sufficient image quality for the visualization of the anterior optic pathway, pituitary gland, pituitary tumor and surrounding tissues. Subsequently NFMA-patients will be evaluated pretreatment and <1week, 6 and 12 months post-treatment, to correlate the loss of visual function with the anatomical changes in the optic nerves and chiasm. The radiological description of the MR-images will be compared with statistical HFA perimetry, visual acuity, OCT and the Visual Functioning Questionnaire.

Study burden and risks

The burden of participation will be a 3T and 7Tesla MRI scans, with contrast injection, combined with an ophthalmic evaluation at four time points. Most of these evaluations (the 3T MRI and the ophthalmic evaluations) are already being performed as part of the standard clinical care, and will therefore not be an additional burden for the patient.

The risks associated with participation are the potential risks involved with

the high magnetic fields present around an MRI scanner. As all subjects will be screened for potential contra-indication for MR-scanning, these risks of this study are effectively removed. There is also a minimal risk associated with the contrast injection. Patients are screened for any previous contrast reactions. If previous reactions have occurred then the patient is excluded from the study to ensure patient safety.

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

Patients diagnosed with a pituitary macro adenoma

Exclusion criteria

1. Age <18 years or >70 years
2. Renal failure or previous allergic reactions to contrast agent
3. Known pathology that could simultaneously effect visual fields e.g. glaucoma
4. Contraindications to MRI scanning, including:
a. Claustrophobia
b. Pregnancy
c. Pacemaker and defibrillator
d. Nerve stimulators
e. Intracranial clips
f. Metallic fragments
g. Ferromagnetic implants
h. Hydrocephalus pump
i. Permanent make-up
j. Tattoos situated above the shoulder region
k. Piercings that cannot be removed
l. Subjects who are unable to lie still e.g. due to Tremor, Parkinson*s disease
m. Severe physical disability (completely wheelchair bound)

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:	Recruitment stopped
Start date (anticipated):	18-04-2018
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	MRI
Registration:	No

Ethics review

Approved WMO Date:	29-01-2018
Application type:	First submission
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	NL61460.058.17

Study results

Date completed:	01-01-2020
Actual enrolment:	4