Evaluation of the pelvic floor patients with Pelvic Organ Prolaps (POP) and controls, using dynamic MRI and Diffusion Tensor Imaging (DTI).

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Ethical review	Approved WMO
Status	Pending
Health condition type	Genitourinary tract disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON33068

Source
ToetsingOnline

Brief title
Dynamic MRI and DTI of the pelvic floor

Condition

- Genitourinary tract disorders NEC

Synonym
prolapse

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diffusion Tensor Imaging (DTI), Dynamic MRI, Pelvic floor, Pelvic Organ Prolapse (POP)

Outcome measures

Primary outcome

The main study endpoint is the assessment of pelvic organ prolapse (POP) with the use of different reference lines and anatomical landmarks by comparing diagnostic outcomes with POP-Q findings.

Secondary outcome

Secondary endpoints are the feasibility of DTI in evaluating pelvic floor musculature and the intra- interobserver variability using reference lines in dynamic MRI.

Study description

Background summary

For the assessment of Pelvic Organ Prolaps (POP) several methods to interpret dynamic MRI are reported in literature. However until now the reference lines and anatomical landmarks which should be used to assess and stage pelvic prolapse are not defined, therefore reliability of the used reference lines should be determined. Secondly, diffusion tensor imaging (DTI) in combination with fiber tracking algorithms has been reported as imaging method for the visualization in human muscle. We hypothesized that DTI can be applied to the pelvic floor musculature for visualization and the potential in identifying abnormalities in POP patients.

Study objective

In this study we aim to evaluate pelvic floor structures in both POP patients and controls with the use of different anatomical landmarks and reference lines in non-invasive dynamic MRI. Additionally we propose to evaluate the

feasibility of DTI in characterizing pelvic floor musculature.

Study design

Prospective pilot study. The study population comprises POP patients and controls that are allocated into 3 groups. All three groups (n=30) will undergo dynamic MRI with additional DTI, of the pelvic floor.

Study burden and risks

Risks for subjects undergoing dynamic MRI examination are minimal, provided precautions have made to prevent examining individuals with contraindications. For this purpose, the routine MRI contra indications form of the AMC will be used. Dynamic MRI is a diagnostic procedure so there are no direct therapeutic effects. A group-related benefit of this diagnostic study is that with the demonstration of feasibility of dynamic MRI and DTI, an applicable non-invasive tool in the detection of disorders of the pelvis could be obtained.

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: Women in the age of 40 * 75 years, with at least a grade 2 prolaps in conformity with the POP-Q guidelines, as scored by the gynecologist. Women who are willing to undergo dynamic MRI and are willing to give informed consent for the study. Sufficient knowledge of the Dutch language to fill out the study questionnaires.
Controls: Women in the age of 18 - 75 years willing to undergo dynamic MRI scan and who are willing to give informed consent. Sufficient knowledge of the Dutch language to fill out the study questionnaire.

Exclusion criteria

Patients and Controls:
-pelvic surgery with related changes to the pelvic floor anatomy.
-Inability to follow instructions of straining pelvic muscles, relaxing pelvic muscles and increasing abdominal pressure.
-Other exclusion criteria are (relative) contraindications to undergo MRI; pacemakers, claustrophobia and pregnancy.

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:	Pending
Start date (anticipated):	01-04-2009
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL27491.018.09