Evaluation of pelvic organ prolapse using upright magnetic resonance imaging

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An explorative study, that will include 15 patients and 15 volunteers without pelvic floor disorders, will be conducted to evaluate the possibilities of an open 0.25T MRI- system to assess the pelvic floor and to get a better understanding of the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Observational non invasive

Summary

ID

NL-OMON45910

Source
ToetsingOnline

Brief title
POP UP MRI - Pelvic Organ Prolapse UPright MRI

Condition

- Uterine, pelvic and broad ligament disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
Pelvic floor dysfunction - Prolapse

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Pelvic organ prolapse, Reference lines, Surgery, Weight bearing MRI

Outcome measures

Primary outcome

The aim of this explorative study is to evaluate existing clinical parameters that are developed for supine MRI (angles, distances, function/composition of the muscle) in upright scanning and to assess how these parameters change between supine and upright MRI scanning in both volunteers without pelvic floor disorders and patients.

Secondary outcome

*To evaluate if there is a correlation between the anatomical severity of POP, as measured with POP-Q, and the parameters obtained with MRI.

*To evaluate if there is a correlation between the parameters obtained from the MR images pre- and post- operative.

*To explore if additional parameters can be defined, based on the upright MRI scan, that may be of interest to the surgeon and outcome of surgical treatment, which can be further tested for their clinical merit in a future trial

Study description

Background summary

Pelvic organ prolapse (POP) is a common condition in middle aged and elderly women. Approximately 10% of women will have surgery for POP and/or urinary incontinence during their lifetime. Surgical correction of the POP is effective but unfortunately in 30% of the cases a residual prolapse occurs. It is unclear why these recurrences occur. One of the theories is that with our traditional physical (gynecological) examination anatomical details of the POP, that are

crucial for surgical repair and success, are missed. In the last decades imaging techniques, like ultrasound and MRI, have been developed to study the anatomy of the pelvis in healthy but also POP patients. MRI offers a superior detail of the organs and muscles under study, but unfortunately imaging of the pelvic floor is performed only in supine position. The effect of gravity, which is crucial to develop POP symptoms, is not taken into account in this supine position. Recently, a low-field MRI system was introduced which offers the possibility to scan the patient in a weight bearing, upright position. If the images obtained with this standing MRI are associated with POP severity and show us the anatomical defects in more detail, this information may be useful to fine tune surgical techniques and reduce recurrences.

Study objective

An explorative study, that will include 15 patients and 15 volunteers without pelvic floor disorders, will be conducted to evaluate the possibilities of an open 0.25T MRI- system to assess the pelvic floor and to get a better understanding of the manifestation of POP in a natural occurring position. This explorative study would enlighten changes in the pelvic floor anatomy and landmarks in supine and standing position. This is observed in the static (in rest) and dynamic (during contraction in the pelvic floor) situation, during a pre- and post-operative scan. The parameters used to interpret the supine imaging are evaluated on usefulness in upright imaging as well as how they change with the positioning. This pilot study will assess the feasibility for a larger study, with the aim to find parameters which are associated with the outcome of prolapse surgery. MRI could give additional information as preoperative diagnostic tool to predict outcome of surgery, e.g. identify those prone to develop recurrence. According to these prognostic parameters obtained with this study, surgical interventions could be adjusted to improve the outcome and reduce the recurrence.

Study design

Prospective cohort study, where the images of 15 patients will be obtained 1-4 weeks before and 6 weeks after surgery. The patients on the waiting list for the prolaps surgery (at MST/ZGT), which meet the inclusion criteria, will be called by the gynaecologist , to ask if the investigator can send them the written information about the study and approach them afterwards. If she is willing to participate, the next consult at the gynecologist after the diagnosis but for the operation, she will sign the informed consent, before the POP-Q in standing and lying position is performed. On the same day (or another), the patient will be asked to be scanned in an open 0.25 T MRI [CE0051] at the University of Twente. During this scan, the participants are positioned in both supine and upright position, where a scan in static and dynamic (contraction and squeezing) situation will be obtained. The duration of the exam itself will be 1 hour.

Also, 15 volunteers without pelvic floor disorders will be recruited by hanging leaflets around the University of Twente asking for volunteers. When people are interested they will have a brief contact with the coordinating investigator who will check whether they meet all requirements. If everything is in order more information regarding the study will be sent to the volunteers and they are invited to the University of Twente for the scans. The volunteer will be scanned with the 0.25T rotatable MRI [CE0051]. The volunteers will be scanned in upright and supine position, in both a static and dynamic (during contraction and squeezing) situation. A possible outcome is that the total number of 15 volunteers will be not reached when a significant difference between patients and volunteers is already apparent at a smaller amount.

Study burden and risks

The burden associated with participation is that volunteers without pelvic floor disorders need to visit the university once for a scan. Patients need to visit the university twice: before and after surgery.

Each appointment will roughly take one hour. To perform the upright scan, the participant needs to stand still for at most 15 minutes. During this position, some people experience dizziness, if this happens the scan can be aborted immediately and the patient is turned back to the horizontal position. Still the risks associated with this MRI examination are negligible. The participant need to empty their bladder 1/2 hour prior to the visit and is preferred not to void after the measurements are completed.

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

For patients:
Signed informed consent
Symptomatic grade 2 pelvic organ prolapse
Planned for surgery (anterior and/or posterior wall repair, Manchester, sacrocolpopexie);For volunteers without pelvic floor disorders:
Signed informed consent
In same age and BMI category as the patient population
At least one vaginal delivery

Exclusion criteria

Previous prolapse surgery
Hip waist >47 cm
Not eligible for MRI, in response to the MRI safety checklist
Inability to stand for 15 minutes, without assistance;Additionally for healthy volunteers:
No prior history of pelvic organ complaints

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-12-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	29-09-2016
Application type:	First submission
Review commission:	METC Twente (Enschede)

Approved WMO

Date:	08-12-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NL57965.044.16