Imaging Pelvic Organ Prolapse with upright MRI

No registrations found.

| Ethical review | Not applicable |
|-----------------------|----------------------------|
| Status | Pending |
| Health condition type | - |
| Study type | Observational non invasive |

Summary

ID

NL-OMON24051

Source NTR

Brief title POP UP MRI

Health condition

Pelvic organ Prolapse

Sponsors and support

Primary sponsor: University of Twente **Source(s) of monetary or material Support:** fund= initiator= sponsor = University of Twente

Intervention

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.

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 postoperative.

• 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 women above 40. Imaging of the pelvic floor with Magnetic Resonance Imaging is performed only in supine position. The effect of gravity, which is crucial to develop POP symptoms, is not taken into account. Recently, a low-field MRI system (0.25T) was introduced which offers the possibility to scan the patient in an upright position.

15 Patients will be scanned in upright and supine position, both in static and dynamic situation(Valsava and contraction). This explorative study will evaluate existing MRI parameters that are developed for supine MRI (angles, distances, function/composition of the muscle) to assess how they change between supine and upright MRI scanning, before and after prolapse surgery. And will correlate the results with the clinical manifestations measured with POP-Q.

Study objective

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 [3, 4]. POP can occur in the anterior, posterior or apical compartment of the vagina. It can happen in a single compartment, but more often multiple compartments are involved. Therefore, several surgical techniques, like anterior colporrhaphia, posterior colporrhaphia, vaginal cuff or cervix fixation are used, alone or in combination. Surgical correction of the POP is effective but unfortunately in 30% of the cases a residual prolapse occurs.[4] 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 [5-8]. 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 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 design

Before prolaspe surgery 6 weeks after prolapse surgery

Intervention

open low field-MRI (0.25T, Esaote), with a tilting function up to 90 degrees

Contacts

Public

NIM group Twente University Judith olde Heuvel Enschede The Netherlands Phone: +31 652172679 **Scientific** NIM group Twente University Judith olde Heuvel Enschede The Netherlands Phone: +31 652172679

Eligibility criteria

Inclusion criteria

- Patients with POP >18 yr
- Symptomatic prolapse
- >Grade 2 POP-Q
- 3 Imaging Pelvic Organ Prolapse with up-right MRI 6-05-2025

- Good knowledge of Dutch language
- Signed informed consent

- Planned for prolapse repair surgery (anterior and/or posterior wall repair, Manchester, sacrocolpopexie)

Exclusion criteria

- Previous prolapse repair surgery
- Inability to stand for 15 minutes, without assistance
- Hip width < 47 cm
- Not allowed to do a maximum Valsalva maneuver because of cardiac or pulmonary disease
- Not eligible for MRI, in response to the MRI safety checklist

Study design

Design

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| Study type: | Observational non invasive |
|------------------------|----------------------------|
| Intervention model: | Other |
| Control: N/A , unknown | |

Recruitment

| NL | |
|---------------------------|-------------|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-09-2016 |
| Enrollment: | 15 |
| Туре: | Anticipated |

Ethics review

Not applicable

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 |
|----------|----------------|
| NTR-new | NL4060 |
| NTR-old | NTR5944 |
| ССМО | NL57695.044.16 |

Study results

Summary results none