Patient research anatomy and pessary therapy

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OBJECTIVE: through MRI research, we want to map the pelvic floor structures that are involved in holding a pessary in place

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON41878

Source
ToetsingOnline

Brief title
PRAP-study

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
descensus, prolapse

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MRI, Pessary therapy, Prolapse

Outcome measures

Primary outcome

Surface of the hiatus

Pubococcygeal line, length cervix, transvaginal length, diameter and defect

musculus levator ani

Secondary outcome

Possible secondary outcomes are: pubococcygeale line, cervix length ,

transvaginal length , diameter and defect musculuis levator ani in relation to

a standard pessary. The final secondary outcomes, we can not determine yet. The

final secondary outcomes will be explored during the analysis of the MRI images

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Study description

Background summary

BACKGROUND: More than 50 percent of the women above 40 years, deal with a prolapse of the bladder, uterus, rectum or a combination. Not all women experience symptoms of their prolapse. For the women who experience symptoms of their prolapse, there are several treatment options. They can choose pelvic physiotherapy, pessary therapy or surgical treatment. 57% of the women with symptoms of their prolapse choose pessary therapy. After 3 years, almost 50 percent of these women quited the pessary therapy. Furthermore, there is also a group of women, where it is not possible to find a suitable pessary. For this reason they are forced to switch to surgical treatment. For optimization of pessary therapy, it is important to have an insight in the pelvic floor structures that are involved in holding a pessary in place. The pelvic anatomy is extremely complex and there are differences in anatomy reported in the current literature and anatomy books. Meanwhile, by improving techniques it is possible to picture the pelvic anatomy better. We will hope to get an answer to the question why it is impossible to find a suited pessary for all women.

Study objective

OBJECTIVE: through MRI research, we want to map the pelvic floor structures that are involved in holding a pessary in place

Study design

STUDY DESIGN: Pilot study

Study burden and risks

The risk for women to participate consists of one extra visit to perform an MRI. An MRI shows no radiation exposure or health risk to the participating women. Women with severe contraindications to MRI such as pacemaker , severe claustrophobia , etc. are excluded. The personal benefit of women to participate in this study is the financial compensation consists of a coupon of 25 euro and refund of travel expenses.

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

- Women with an anterior vaginal wall prolaps and/or prolapse of the cervix minimal POP-Q stage II, who are minimal one year treated with pessarytherapy and have no more prolapse complaints and where the pessary shows a good corrections of the prolapse.
- Woman with an anterior vaginal wall prolaps and/or prolapse of the cervix minimal POP-Q stage II, who choose pessarytherapie, but it is not possible to find a pessary that show a good correction of the prolapse and give no more prolapse complaints.

Exclusion criteria

- Age of 18 years or more
- Patients who are mentally incompetent
- Patients with a posterior vaginal wall prolaps as leading part and where the posterior vaginal wall prolaps the indication is for therapy
- Patients with former prolapse surgery
- Contra-indications for MRI

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):	03-06-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	02-09-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL51656.068.15