Transvaginal mesh repair of recurrent vaginal prolaps (prolift technique); a cross sectional study of 65 cases in a Dutch teaching hospital.

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1. to measure anatomical outcome after vaginal repair with mesh (Prolift technique) and compare with pre-operative scorings, using POP-Q test.2. to estimate quality of life, sexual functioning, urogenital en defecatory symptoms after vaginal repair...

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

Summary

ID

NL-OMON35178

Source
ToetsingOnline

Brief title
Follow up study after meshimplantation for recurrent vaginal prolapse

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
Prolapse, vaginal prolapse

Research involving
Human

Sponsors and support

Primary sponsor: Overige Ziekenhuizen

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

Intervention

Keyword: anatomical outcome, mesh surgery, recurrent vaginal prolapse, subjective outcome

Outcome measures

Primary outcome

Using the POP-Q test during gynecological examination the anatomical outcome will be assessed. These outcomes will be compared to those prior to the correction of the pelvic floor dysfunction.

Secondary outcome

- General quality of life will be assessed by using a standardized measurement (Rand-36).
- Urinary and defecatory symptoms will be analyzed by using validated disease specific questionnaires concerning quality of life (Urogenital Disease Inventory, Defecation Distress Inventory and Incontinence Impact Questionnaire).
- PISQ-12 translated to Dutch will be used to assess sexual functioning, where as some selected items from the *Vragenlijst Seksuele Disfuncties* will complement PISQ-12 questionnaire.
- Satisfaction with outcome after surgery among the women will be assessed by asking them to answer the question if they are satisfied by the result of the surgical procedure. Multiple choice answers will be provided by the Likert Scale that ranges from very dissatisfied tot very satisfied in 5 points. For the analysis of these answers, we will dichotomize those answers and divide them in very dissatisfied/dissatisfied/moderately satisfied and satisfied/very

satisfied.

Remaining secondary endpoint is the time needed for complete recovery. The women will be asked after how many days, weeks or months they felt completely recovered after surgery. Likert Scale will also be used to range five different answers: within 2 weeks, 2-4 weeks, 1- months, 3-6 months and beyond 6 months. Dichotomizing these answers will also take place in this analysis, within 3 months and beyond 3 months.

Study description

Background summary

Uterovaginal prolapse is a frequent disorder among women, especially for those who experienced one or more vaginal births . In the Netherlands, 40% of the women who have reached the age of 45 years or beyond have uterovaginal prolapse . In case of 10% of these women will need a surgical approach as a remedy for this health problem, rather than the conservative non-surgical treatment.

Historically, the most frequent way of treating women with uterovaginal prolapse that needs surgery, is vaginal hysterectomy with, when needed, surgical repair of any other pelvic organ prolapse. Even with various other techniques developed over the past decades, there is still no gold standard available . Unfortunately, recurrence of prolapse after a prior operation is 29% among these women and frequently re-operation is necessary .

One of the new techniques which have been developed in the past decades involves the use of a nonabsorbable mesh , with the possibility to combine the repair of anterior, posterior and apical compartment prolapse. Literature reveals a high success rate when using this approach to correct the pelvic floor dysfunction. However, complications are also reported. One of them is called mesh erosion of the visceral wall and related morbidity. This is reported to occur in 4.6-10.7% of patients. Other complications of this procedure are perianal pain, exposure of the graft, vaginal adhesions, infection, fistulas and dyspareunia6.
Although this procedure is widely used by gynecologists, there have been a few randomized trials that compared mesh repair to other techniques7,9,10. Outcome of these studies mainly reflect anatomical results. Subjective outcome is still underexposed and are concerning quality of life, urogenital as well as

defecatory symptoms and sexual functioning .

In a cross-sectional study we will observe anatomical outcome after a procedure using a mesh to discontinue pelvic organ prolapse. Besides these outcomes, we will also assess subjective outcomes. These will include quality of life, urogenital and defecatory symptoms and sexual functioning. This study will assess the long term effects of vaginal mesh for prolapse, with minimum follow-up of one year.

Study objective

1. to measure anatomical outcome after vaginal repair with mesh (Prolift technique) and compare with pre-operative scorings, using POP-Q test.
2. to estimate quality of life, sexual functioning, urogenital en defecatory symptoms after vaginal repair with mesh (Prolift technique), in women with uterovaginal prolapse.

Study design

The design of the study will be a cross-sectional study, in Medisch Centrum Leeuwarden. The aims of this study are to assess objective outcomes and different subjectives outcomes in women who underwent correction of uterovaginal prolapse through vaginal repair with mesh. The patients who are included in this study will receive questionnaires at home about quality of life, sexual functioning, urogenital and defecatory symptoms, subjective outcomes. Once they filled in the questionnaires, objective outcome will be assessed by a gynecological examination in the hospital, POP-Q included.

Study burden and risks

Regulation statement
This study and its researchers will follow the principles of the Declaration of Helsinki and those of the Medical Research Involving Human Subjects Acts (WMO).

Recruitment and consent
Patients who are eligible for this study will be approached by the research student, who will sent them written information about the procedure and aims of this study. When patients agree to be in this study, they receive the questionnaires at their home address and thereby an appointment for OPD consultation will be made for the gynecological examination.
The aim of this study is to assess anatomical and subjective outcome after surgery, therefore interventions will not take place. As for any other treatment decisions, these study results will not influence the outcome of it.
To obtain informed consent of all the patients individually, should be necessary. This study proposal will be submitted by the committee of ethics of Medisch Centrum Leeuwarden for ethical clearance.

Benefits and risk assessment
- Patients will be asked to fill in five questionnaires, this will take them about 40 minutes on average of their time.
- Patients will visit the hospital one time to hand over their questionnaires, when necessary discuss any indistinctiveness of the questionnaires, and undergo gynecological examination.
- No interventions will take place during the gynecological examination.

Contacts

Public
Selecteer

Henri Dunantweg 2
8901 BR Leeuwarden
NL
Scientific
Selecteer

Henri Dunantweg 2
8901 BR Leeuwarden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women who underwent mesh implantation surgery for recurrent vaginal prolapse in Medisch Centrum Leeuwarden between April 2008 and April 2011.

Exclusion criteria

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Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2012
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO

Date:	29-03-2012
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL38899.099.11