Long-term follow-up of the prospective and comparative study of the performance of tension free vaginal mesh (ProliftTM) versus conventional pelvic organ prolapse surgery in recurrent prolapse

Published: 28-04-2014
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To asses the effectiveness of surgery 7 and 10 years after conventional vaginal POP surgery compared with tension free vaginal mesh.

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

Summary

ID

NL-OMON40299

Source
ToetsingOnline

Brief title
VROUW 1 follow-up

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
recurrent pelvic organ 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: outcome, pelvic organ prolapse, surgery, vaginal mesh

Outcome measures

Primary outcome

Effectiveness of surgery 7 and 10 years after conventional surgery compared

with tension free vaginal mesh.

Success is defined as a *composite outcome*: pelvic organ prolapse POPQ ,

leading edge < hymen and no bulge symptoms and no re-operation for POP.

Secondary outcome

Long-term complications of both techniques, with special interest in pain and

(de novo)-dyspareunia and re-operation.

Study description

Background summary

Pelvic organ prolapse (POP) is highly prevalent in the female population. There is a high recurrence rate after vaginal POP surgery with native tissue (20-60%). Placement of vaginal mesh aims to reduce this high recurrence rate. A randomised controlled trial was performed in 2006-2008 (Vrouw 1 trial). In this study follow-up was 12 months and the focus of the outcome was on anatomic results.
There are several studies suggesting a more favorable outcome of pelvic organ prolapse surgery when vaginal mesh is used, but the follow-up of these studies is short (12 to 36 months)(altman 2011, Nguyen 2008, menefee 2011, nieminen 2010, sivaslioglu 2008, vollebregt 2011, Withagen 2011, Halaska 2012). There is only one single-armed cohort study with 5 year follow-up, describing 84% success (Jacquetin 2013).
Complications of the grafts are an important issue, especially exposure,

chronic pain and dyspareunia are complications that are ascribed to mesh, although chronic pain and dyspareunia are also seen after POP surgery without mesh (IGZ rapport, Withagen 2011, Vollebregt 2011, Milani 2013).

In conclusion the long-term results are scarce in regard to objective (anatomic) and subjective (patient reported outcomes) efficacy and complications of tension free vaginal mesh repair in compare with conventional vaginal POP repair. It is also important to know whether native tissue repairs are associated with a higher re-operation rate at the long term, when compared to mesh surgery.

Study objective

To asses the effectiveness of surgery 7 and 10 years after conventional vaginal POP surgery compared with tension free vaginal mesh.

Study design

Long-term follow-up of a previous prospective, multicentre, randomized, single blinded study (Vrouw 1 trial)

Study burden and risks

Nature and extent of the burden:
Follow-up visit 7 years. This includes gynaecological examination, including a 3D perineal ultrasound and questionnaires.
Follow-up visit 10 years. This includes gynaecological examination and questionnaires.

"Risks": time consuming. Extra gynaecological investigation.

Benefit: Women already participated in the study and since the media attention and health inspectorate report, there has been a lot of anxiety and disturbance about mesh. By participating in the present study, patients will have an extra check for complications.

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

a. The study population is already selected and randomisation and surgery already have taken place (Withagen 2011, Vrouw 1 trial).
b. Subject is willing to return for follow-up evaluation and/or QoL questionnaires completion at 7 years and/or 10 years after surgery.

Exclusion criteria

a. Subject is unwilling or unable to complete questionnaire and/or return for evaluation
b. Presence or treatment of malignancy in the pelvis / lower abdomen

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-11-2014
Enrollment:	190
Type:	Actual

Ethics review

Approved WMO Date:	28-04-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-08-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-02-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL46834.091.14