Efficacy of revision of mesh surgery in patients with complications after treatment with vaginal synthetic mesh.

Published: 23-02-2015
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To evaluate the subjective and objective cure after surgical re-intervention due to mesh complications in our clinical setting in order to optimize therapy.

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

Summary

ID

NL-OMON44885

Source
ToetsingOnline

Brief title
REMESH

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
mesh complications

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: complications, prolaps, surgery, vaginal synthetic mesh

Outcome measures

Primary outcome

Subjective improvement at the study visit, measured by PGI-I.

Secondary outcome

- Disease specific quality of life at study visit.

- Re- interventions after the *mesh revision*

- Anatomical cure of prolapse, measured with POPQ

Study description

Background summary

Pelvic Organ Prolapse (POP) is a common condition amongst women worldwide with a major impact on quality of life. Various operative procedures for POP exist, however the perfect operation hasn*t been found. Many women suffer from recurrence of prolapse and re-operation is common (29%). The high failure rates of conventional surgery for POP led to innovation in pelvic floor surgery and the introduction of the synthetic vaginal mesh system (TVM) in 2004. Here after many mesh systems were developed and marketed. Clinical studies show that restoration of anatomy with synthetic mesh is superior to conventional surgery, however mesh surgery has its own mesh related complications.
The most common mesh-related complication is mesh exposure. It has been described that approximately 10% of women operated with synthetic mesh experienced mesh exposure within 12 months of surgery and more than half of these women required surgical correction in the operating room. Furthermore reports of pain associated with mesh shrinkage, causing vaginal shortening and tightening and persistent pain despite mesh removal were found in literature.
In the Netherlands, the Academic Medical Center is a tertiary referral center for mesh related complications. Between 2009 and 2014, fifty-six women presented to our clinic, because of exposure of vaginal mesh or mesh-related pain. These women have been managed surgically in our center. Either the exposure was excised and closed, or mesh has been removed or cut to relieve pain.
We plan to execute this study to measure the effectiveness of surgical mesh

revision in case of mesh related complications in order to optimize treatment.

Study objective

To evaluate the subjective and objective cure after surgical re-intervention due to mesh complications in our clinical setting in order to optimize therapy.

Study design

A retrospective single-arm observational study in two Dutch teaching hospitals with a special interest in uro-gynaecology.

Study burden and risks

Patients will be asked to visit our clinic. During this extra visit patients will be asked to fill out validated questionairres. Furthermore a strutured interview and a pelvic exam will be performed. The visit will take about 45 minutes.

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

All patients that have been operated between 2009 and 2014 in the Academic Medical Center or Bergmanclinics Vrouwenzorg, because of complications due to vaginal mesh surgery (exposure or pain).

Exclusion criteria

Patients with mesh compliations that haven't been operated because of this complication.

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):	23-02-2015
Enrollment:	53
Type:	Actual

Ethics review

Approved WMO

Date:	23-02-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL51746.018.14