A PROSPECTIVE AND COMPARATIVE STUDY OF THE (COST) EFFECTIVENESS OF TENSION FREE VAGINAL MESH PLUS MONOCRYL (PROLIFT+MTM) VERSUS CONVENTIONAL VAGINAL PROLAPSE SURGERY IN PRIMARY PROLAPSE

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON35003

Source
ToetsingOnline

Brief title
VROUW 2

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
pelvic organ prolapse

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Johnson & Johnson Pharmaceutical

Intervention

Keyword: complications, efficacy, mesh, pelvic organ prolapse

Outcome measures

Primary outcome

The main outcome is the percentage of patients with objective anatomical success (POP stage <2) after 24 months.

Secondary outcome

As secondary outcome the subjective improvement in quality of life will be measured by generic (EQ-5D) and disease-specific (UDI, DDI, IIQ and PFDI20) quality of life instrument. Sexual functioning will be measured by generic (FSFI) and disease specific (PISQ12) questionnaires. Complications will be monitored with special notice for pain (Mc Gill pain questionnaire) Recovery will be measured with the Recovery index 10. The economical endpoint is short term (2 year) incremental cost-effectiveness in terms of costs per additional year free of prolapse and costs per QALY gained.

Study description

Background summary

Pelvic organ prolapse is highly prevalent in the female population. The incidence of pelvic organ prolapse increases with age, so the longer life

expectancy of women may cause pelvic organ prolapse to become an even more major health issue. The recurrence rate of pelvic organ prolapse after surgical treatment is high. The recurrence rate of the anterior vaginal wall prolapse after an anterior colporrhaphy is 30%-45%. The posterior vaginal wall prolapse recurrence rate after a posterior colporrhaphy is 12-25%. This emphasizes the clinical need for improvement of the surgical techniques currently used. Placement of a mesh aims at reducing the recurrence rate (2-11%).

Study objective

To compare the clinical and cost effectiveness of the Tension free Vaginal Mesh + Monocryl (Prolift+MTM) with the standard vaginal prolapse surgery (i.e. fascial placation). A secondary objective is to track the post-operative and long-term complications of both procedures. A third objective is to evaluate recovery after surgery

Study design

This study is a prospective, multicentre, randomized, non-blinded study between Tension free Vaginal Mesh + Monocryl (Prolift+MTM) and standard vaginal prolapse surgery (i.e. fascial plication).

Intervention

Prolapse surgery with tension free vaginal mesh + Monocryl (Prolift + M) versus conventional vaginal prolapse surgery.

Study burden and risks

Burden associated with participation: complete a disease specific Quality of life questionnaire 4 times, complete a recovery index questionnaire 3 times. Visit the hospital 4 times after the surgery (this is 2 times more often than patients not participating in the study)

Since subjects are selected from subjects already agreeing to complete a surgical procedure, the additional risks of participation in this study are low.
These risks include tissue erosion (vaginal, rectal or bladder), vaginal pain/dyspareunia.

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

primary pelvic organ prolapse (anterior and/or posterior compartment) POP stage II or more
age >44 years

Exclusion criteria

pregnancy
age < 45 years
previous prolapse surgery
blood coagulation disorders
a compromised immune system or any other conditions that would compromise healing
unwilling or unable to return for evaluation
Previous irradiation
Presence of any malignancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-01-2011
Enrollment:	176
Type:	Actual

Ethics review

Approved WMO Date:	29-07-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-11-2011
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
Other	dit protocol wordt binnenkort geregistreerd in clinicaltrials.gov
CCMO	NL31706.091.10