Pelvic organ prolapse in general practice: effects of pelvic floor physiotherapy and of pessary treatment

Published: 15-12-2009
Last updated: 04-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Genitourinary tract disorders NEC
Study type	Interventional

Summary

ID

NL-OMON33065

Source
ToetsingOnline

Brief title
Genital prolapse study

Condition

- Genitourinary tract disorders NEC
- Uterine, pelvic and broad ligament disorders

Synonym
cystocele and rectocele, pelvic relaxation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMw Programma Alledaagse Ziekten

Intervention

Keyword: General practice, Pelvic floor physiotherapy, Pelvic organ prolapse, Pessary

Outcome measures

Primary outcome

The primary outcome parameter is the score on the Pelvic Floor Distress Inventory (which measures prolapse-related symptoms) and the satisfaction with the results of the treatment (the global perception of improvement).

Secondary outcome

Secondary outcome parameters are the quality of life (condition specific and general) and the degree of prolapse and the function of bladder and bowel. Also, the number of women in which a succesful fitting of a pessary is possible will be recorded and the number of referrals to secondary care. The acceptance of the treatments and the side effects will be assessed, just as the costs of the treatments under study.

Study description

Background summary

A pelvic organ prolapse (genital prolapse) is a condition of which the prevalence increases significantly after the menopause. Different stages of severity can be distinguished and it may cause a range of symptoms which are partly specific and partly atypical. The prevalence of pelvic organ prolapse is 10-15 % in older women and it is a not life- threatening but potentially very invalidating condition. It has a negative influence on the quality of life of affected women because it causes physical and psychological problems and interferes with sexuality. Only a minority of women ask for help for their symptoms.
Because pelvic organ prolapse is a disorder of older women, there is a need for research concerning conservative, non-surgical treatments. Operative procedures for prolapse may be contra-indicated in older women beacuse of co-morbidity or

vulnerability. However, the effects of conservative treatments like pessaries and pelvic floor exercises have not been studied adequately. This project aims at filling the gap in our knowledge by comparing conservative treatments of genital prolapse. This is very relevant for general practitioners as they treat 75 % of the women with a pelvic organ prolapse. It is also very relevent for the growing category of older patients for whom an operation is not an option. Given the lack of evidence on the effects of conservative treatments for genital prolapse, the general practitioner currently has to guess which treatment should be advised.

Study objective

The objective of the project is to study the effect of conservative, non-surgical treatments of pelvic organ prolapse in a randomized clinical trial. The treatments under study, pessaries and pelvic floor physiotherapy, aim at reducing the symptoms of a genital prolapse, at improving the function of the plevic floor muscles, at preventing the prolapse from getting worse and at reducing the need for operative procedures. The study focusses on the age category with the highest prevalence and incidence of prolapse symptoms, that is postmenopausal women. Because many women with prolapse symptoms hesitate to seek help for their problems, all women of 55 and older will be actively approached.
The following questions will be studied:
1.What are the effects and what are the costs of treating older women with a mild prolapse with pelvic floor exercises compared to a expectant policy
2.What are the effects and what are the costs of treating older women with a moderate prolapse with pelvic floor exercises compared to pessary treatment.

Study design

The design of the study is an open label randomized clinical trial which aims at studying the effects of conservative treatments of a pelvic organ prolapse in older women. The trial consists of two parts: in the first part the effect of pelvic floor physiotherapy will be compared to wait and see in women with a mild prolapse. In the second part, pessary treatment will be compared to pelvic floor physiotherapy in women with a moderate prolapse.
Follow up measurements will take place 3 months after the inclusion in the trial or the start of the treatment, respectively and after 1 and 2 years.

Intervention

Women, who have a pelvic organ prolapse according to the urogynaecological examination, will be included in one of two intervention studies, depending on the degree of prolapse:
1. A study in women with a mild prolapse: the deepest point of the prolapse remains above the hymenal ring during maximal Valsalva. (stage 1 and mild stage

2 in the POP-Q ordinal scale). In this category of women the effects of pelvic floor exercises will be compared with a wait and see strategy. Participants in this part of the study will be randomized to treatment by a pelvic floor physiotherapist or to no active treatment, after informed consent
2. A study in women with a moderate prolapse: the deepest point of the prolapse passes the hymenal ring during maximal Valsalva. (advanced stage 2 and stage 3 in the POP-Q ordinal scale). In this category of women the effects of pelvic floor exercises will be compared pesary treatment. Participants in this part of the study will be randomized to treatment by a pelvic floor physiotherapist or to treatment with a pessary, after informed consent.

Study burden and risks

All diagnostic and therapeutic procedures applied in this study, are standard procedures in evaluating and treating pelvic organ prolapse. All examinations are non-invasive and will cause no harm to the patient. The pelvic floor exercises have no adverse effects. Treatment with a pessary may cause irritation of the vaginal wall or vaginal discharge in case of an imperfect fit. The patients in the pessary group will be instructed to contact the resaerch physician or their own GP in case of symptoms related to the pessary. Besides, they will be monitored every three months to detect symptoms in an early stage (as is standard care in the Netherlands in women who wear pessaries).
The burden of the study for the patients consists of filling in questionnaires, of a urogynaecological examination and, depending on the treatment for which they are randomised, of visiting a plevic floor physiotherapst or the fitiing and wearing of a pessary. These treatments belong to the usual care options in general practice in case of a pelvic organ prolapse.

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

Symptomatic prolapse, able to fill in a Dutch questionnaire, mobile enough to visit a pelvic floor physiotherapist, informed consent

Exclusion criteria

Severe cognitive decline, serious or teminal disease (according to the general practitioner), urogynaecological malignancies, being currently treated for urogynaecological disorders, conservative prolapse therapies in the preceding year, severe (stage 4) prolapse.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	274
Type:	Anticipated

Medical products/devices used

Generic name:	supportive pessary
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL29155.042.09