Verzakkingsklachten in de huisartspraktijk: de effecten van bekkenfysiotherapie en pessariumbehandeling.

Gepubliceerd: 08-10-2009 Laatst bijgewerkt: 18-08-2022

Pelvic organ prolapse (POP) is a common disorder in postmenopausal women, causing a variety of symptoms and influencing quality of life. A large portion of women with POP in the Netherlands are treated by their general practitioner (GP), but...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25669

Bron
Nationaal Trial Register

Verkorte titel
POPPS

Aandoening

Pelvic organ prolapse
Urogenitale prolaps (Nederlands)

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG), departments of general practice and epidemiology
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pelvic Floor Distress Inventory (PFDI-20) score after 3, 12 and 24 months.

Toelichting onderzoek

Achtergrond van het onderzoek

Pelvic organ prolapse (POP) is a common disorder in postmenopausal women, causing a variety of symptoms and influencing quality of life. A large portion of women with POP in the Netherlands are treated by their general practitioner (GP), but evidence on which to base the choice between watchful waiting, pelvic muscle training (PMT) and pessary treatment is lacking.

This study aims to investigate the effects and costs of PMT compared with watchful waiting in women with mild POP, and PMT compared with pessary treatment in women with moderate POP.

In this randomized controlled clinical trial, all women in 35 selected GP offices who are older than 54 years will receive a questionnaire concerning POP symptoms. In women with POP symptoms who want to participate in the study, presence and stage of prolapse will be determined using the pelvic organ prolapse quantification (POP-Q). Symptomatic women with POP will be included in the study after informed consent.

Women with mild POP will either receive PMT or watchful waiting, women with moderate POP will either receive PMT or pessary treatment.

Primary outcome measure is the score on the Pelvic Floor Distress Inventory (PFDI), a questionnaire that measures POP symptoms and bother. Secondary outcome measures are Global perception of improvement and VAS score of improvement of the symptoms, quality of life, POP stage and cost of treatment.

Follow up visits will be at 3, 12 and 24 months.

Doel van het onderzoek

Pelvic organ prolapse (POP) is a common disorder in postmenopausal women, causing a variety of symptoms and influencing quality of life. A large portion of women with POP in the Netherlands are treated by their general practitioner (GP), but evidence on which to base the choice between watchful waiting, pelvic muscle training (PMT) and pessary treatment is lacking.

This study aims to investigate the effects and costs of PMT compared with watchful waiting in women with mild POP, and PMT compared with pessary treatment in women with moderate POP.

We expect that treatment of POP by pelvic muscle training or pessary use will result in a decrease in the amount and severity of POP symptoms and will improve quality of life at reasonable costs.

Onderzoeksopzet

Follow up visits will be at 6, 12 and 24 months.

Women being treated with a pessary will have recheck visits every 3 months.

Onderzoeksproduct en/of interventie

Women with POP-Q stages I and II not beyond the hymen will either receive PMT or watchful waiting.

Women with POP-Q stages II beyond the hymen and III will either receive PMT or pessary treatment.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Women older than 54 years;

2. Symptomatic stage I, II or III POP (pelvic organ prolapse quantification (POP-Q));

3. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Cognitive impairment (eg dementia);

2. Poor physical condition (according to their GP);

3. Urogynecological malignancy;

4. Treatment of POP within the last 12 months;

5. Not being able to visit the general practitioner's of physiotherapist's office due to impaired mobility.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	14-10-2009

Aantal proefpersonen:	366
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-10-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1930
NTR-old	NTR2047
Ander register	ZonMw : 80-81000-98-089
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A