Research into effectiveness and costs concerning the use of oestrogen before and after vaginal prolapse surgery in women after menopause.

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

Samenvatting

ID

NL-OMON28340

Bron
NTR

Verkorte titel
EVA

Aandoening

Pelvic organ prolapse
Prolapse surgery

Prolaps
Verzakking
Prolapschirurgie
Prolapsoperatie

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: Leading the Change

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Subjective cure (PGI-I)

Toelichting onderzoek

Achtergrond van het onderzoek

Worldwide 30% of all pelvic organ prolapse (POP) operations are performed for recurrent prolapse. The costs associated with the treatment of recurrent POP are huge, and the burden by the women who encounter recurrent POP has negative impact on quality of life. Oestrogen has a proven beneficial effect on the healing process of the vagina after POP surgery. It is easy to administer, cheap, and easy to obtain. Based on research performed in our institute, it has been shown that vaginal oestrogen in low dosages is very efficient: in women with vaginal atrophy the vaginal wall thickness doubles after 6 weeks of use. There is also evidence that oestrogen improves wound healing, by reducing the inflammatory responses and promoting angiogenesis. Although there is benefit that vaginal oestrogen therapy improves pelvic floor function following POP surgery, and improves healing conditions, there is no comparative study to evaluate whether vaginal oestrogen therapy before and after POP surgery improves outcome. Based on the theoretical background, such study would need to be performed in postmenopausal women as they have low levels of oestrogen. For that reason, we propose a multicentre randomised controlled trial comparing perioperative vaginal oestrogen therapy to placebo in postmenopausal women undergoing POP surgery. Based on our own research, data in literature, and theoretical background, the reduction in recurrent POP surgery is expected to be 15% or more, which would implicate a cost-saving of 5.1 million euros per year in the Netherlands.

Doel van het onderzoek

This study aims to comprehensively compare the effectiveness and costs of perioperative topical oestriol for postmenopausal women undergoing POP surgery. In this trial, the perioperative use of oestriol is considered superior to placebo which would result in reduction of recurrence risk of vaginal prolapse with secondary cost reduction.

Onderzoeksopzet

Timepoint 1: baseline (4-6 weeks preoperative)
Timepoint 2: 3 months postoperative

Timepoint 3: 12 months postoperative

Onderzoeksproduct en/of interventie

Intervention group:
The intervention group receives 0,5 mg oestriol cream (1mg/g, topical administration) 4-6 weeks preoperative till 12 months
postoperative. (First 2 weeks 0,5 mg once a day, thereafter 0,5 mg twice per week).

Control group:
The other group receives a placebo cream (equal schedule as intervention group).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

- Postmenopausal women (>1 year amenorrhoea) with a minimum age of 18 years old
- Pelvic organ prolapse; POP Quantification stage 2 or higher
- Women that will undergo primary POP surgery with native tissue repair; including at least anterior OR posterior vaginal wall repair

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Previous POP surgery in concerning compartment
- Prolapse repair using mesh
- Current vaginal infection
- Use of oestrogens in the past 12 months
- Contraindication for use of topical oestrogen
- Known, past or suspected oestrogen-dependent malignant tumours (e.g. breast cancer, endometrial cancer)
- Insufficient knowledge or understanding of the Dutch language

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2018
Aantal proefpersonen:	300
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-02-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55535
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6853
NTR-old	NTR7031
CCMO	NL62764.018.17
OMON	NL-OMON55535

Resultaten