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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28340

Source
NTR

Brief title
EVA

Health condition

Pelvic organ prolapse
Prolapse surgery

Prolaps
Verzakking
Prolapschirurgie
Prolapsoperatie

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: Leading the Change

Intervention

Outcome measures

Primary outcome

Subjective cure (PGI-I)

Secondary outcome

- Compound measure:
[1] no prolapse in compartment of surgery or past the hymen
[2] no bothersome complaints of prolapse
[3] no re-intervention for prolapse in the compartment of surgery within the follow-up period;
- QALY (EQ-5D-6L);
- Disease specific quality of life: micturition, defecation and sexual function;
- Vaginal pH;
- Signs of vaginal atrophy during gynaecological examination;
- Complaints of vaginal atrophy;
- Morbidity and adverse events;
- Interventions for pelvic floor pathology;
- Costs;
- Adherence to treatment.

Study description

Background summary

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.

Study objective

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.

Study design

Timepoint 1: baseline (4-6 weeks preoperative)
Timepoint 2: 3 months postoperative
Timepoint 3: 12 months postoperative

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2018
Enrollment:	300
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-02-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55535
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results