ISRCTN46661996 https://doi.org/10.1186/ISRCTN46661996

# Local oestrogen treatment in postmenopausal women undergoing pelvic organ prolapse surgery

**Submission date**
28/05/2015

**Recruitment status**
No longer recruiting

**Registration date**
28/05/2015

**Overall study status**
Completed

**Last Edited**
14/06/2023

**Condition category**
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Pelvic organ prolapse is the bulging or drooping of any pelvic organs (bladder, uterus, bowel) into the vagina. Prolapse is a common gynaecologic condition caused by weakening of the supporting tissues of the pelvic floor. Prolapse operations may include vaginal hysterectomy (removal of the womb vaginally) or pelvic floor repair (tightening of the front or back wall of the vagina or support the top of vagina). Hormone (oestrogen) replacement might improve the condition of the vaginal wall and help strengthen the pelvic floor, reducing complications of surgery eg water infections and improving the quality of the surgical repair. Postmenopausal women with vaginal dryness are sometimes treated with oestrogen in the form of tablets (pessaries) they insert into the vagina. However, it's not known whether vaginal application of oestrogen might reduce complications during operations for prolapse and improve long term postoperative outcomes. The aim of the LOTUS study will be to test whether treatment with vaginal oestrogen pessaries, improves prolapse related quality of life after surgery. We also want to see whether surgical complications are reduced and sexual function improved in these patients. Before starting a large study, it's important to rehearse the trial plan in a small feasibility study (treatment v no treatment), to see, for example, how many eligible women could be recruited to the study, how many would be willing to have treatment assigned at random, and how many would stick with the treatment for a specified period of time. This feasibility study will also help calculate the number of patients required for a definitive study, and the resources needed.

Who can participate?
Postmenopausal women about to undergo surgery for a pelvic organ prolapse and that have not had HRT in the last 12 months.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention) are put on a 6 week course of oestradiol (once daily for 2 weeks followed by twice weekly for four

weeks) and then again twice weekly from 6-26 weeks after surgery. Those participants in group 2 (control) are not given the oestradiol treatment. All participants are then followed up 12 months after the surgery to assess their quality of life.

What are the possible benefits and risks of participating?
To date, there has been no robust data on the benefits of pre and postoperative oestrogen treatment in postmenopausal women undergoing POP surgery. A Cochrane review published in 2010 did not find any clear evidence to suggest whether oestrogens help in reducing the symptoms of POP.3 However due to frequent use, it was recommended that adequately powered RCTs with long term follow up is needed to identify benefits or risks.

Where is the study run from?
University of Birmingham Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
July 2015 to July 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mrs Lisa Leighton

# Contact information

### Type(s)
Public

### Contact name
Mrs Lisa Leighton

### Contact details
University of Birmingham
Birmingham Clinical Trials Unit
Division of Medical Sciences
Robert Aitken Institute
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United Kingdom
B15 2TT

# Additional identifiers

### Clinical Trials Information System (CTIS)
2014-000179-18

### Protocol serial number
18990

# Study information

## Scientific Title
Local Oestrogen Treatment in postmenopausal women Undergoing pelvic organ prolapse Surgery (LOTUS) feasibility study

## Acronym
LOTUS

## Study objectives
The aim of the LOTUS study is to establish whether treatment with vaginal oestrogen pessaries, for 6 weeks before and 52 weeks after prolapse repair surgery, improves prolapse related quality of life one year following surgery. We also want to assess whether surgical complications are reduced and sexual function improved. This will require a clinical trial of several hundred women, half of whom would receive oestrogen and half who would receive no treatment. This feasibility study is being conducted in order to help calculate the number required for a definitive study, and the resources needed.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
West Midlands Ethics Committee, 28/04/2015, ref: 15/WM/0092

## Primary study design
Interventional

## Study design
Randomised; Interventional; Design type: Not specified, Treatment

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Topic: Reproductive health and childbirth; Subtopic: Reproductive Health and Childbirth (all Subtopics); Disease: Reproductive Health & Childbirth

## Interventions
Intervention group (Group A): This will comprise of 6 weeks course of oestradiol 10 µg preoperatively per vaginum (once daily for 2 weeks followed by twice weekly for four weeks) and then 10µg oestradiol per vaginum twice weekly from 6-26 weeks postoperatively
Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

## Intervention Type
Biological/Vaccine

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Not provided at time of registration

### Primary outcome(s)
Current primary outcome measure as of 04/02/2020:
To obtain estimates for important aspects of the protocol to allow the development of a definitive
trial

Previous primary outcome measure:
Improvement in prolapse related QoL at 12 months as assessed by PFDI SF20.

### Key secondary outcome(s)
Current secondary outcome measures as of 04/02/2020:
1. Assessment of the effectiveness of patient identification and screening processes
3. Assessment of the effectiveness of the randomization process of patients
4. Evaluation of robustness of data collection processes
5. The proportion of patients followed up at six months
6. Derivation of the preliminary data from clinical outcome measures (e.g.PFDI-SF20) to inform the sample size calculation for the substantive study

Previous secondary outcome measures:
Improvement sexual function related quality of life (QoL) at 12 months with the use of PISQ 12
1. Reduction of intraoperative complications like tearing or button holing of the vagina and blood loss
2. Reduction in the incidence of surgical wound infection and urinary tract infection postoperatively
3. Validate Patient Global Impression of Improvement (PGI-I)19 in relation to the POP surgery, PFDI SF20 and PFIQ-7

### Completion date
01/07/2017

## Eligibility

### Key inclusion criteria
1. Postmenopausal women
2. Consented to undergo surgical intervention for pelvic organ prolapse
3. Have not received HRT in the last 12 months
4. Willing to be randomised
5. Give written informed consent; Target Gender: Female; Upper Age Limit 90 years ; Lower Age Limit 30 years

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit

30 Years

### Upper age limit
90 Years

### Sex
Female

### Total final enrolment
100

### Key exclusion criteria
1. Previous breast or uterine malignancy or other hormone dependent neoplasms
2. Genital bleeding of unknown origin
3. Previous thromboembolic episodes in relation to oestrogen therapy
4. Women who cannot understand speak or write in English
5. Women known to be allergic to any of the components of vaginal oestrogens
6. Two or more episodes of culture positive UTI in the last 6 months
7. Previous POP surgery
8. Voiding dysfunction(PVR>150ml)
9. Current or previous POP surgery involving mesh

### Date of first enrolment
01/07/2015

### Date of final enrolment
01/07/2017

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Birmingham Women's Hospital (Lead site)**
Mindelsohn Way
Birmingham
United Kingdom
B15 2TG

### Study participating centre
**Croydon University Hospital**
530 London Road
Croydon
Surrey

United Kingdom
CR7 7YE

**Study participating centre**
**Medway Maritime Hospital**
Windmill Road
Gillingham
United Kingdom
ME7 5NY

**Study participating centre**
**Basingstoke and North Hampshire Hospital**
Aldermaston Road
Basingstoke
Hampshire
United Kingdom
RG24 9NA

**Study participating centre**
**Queen Alexandra Hospital**
Southwick Hill Road
Portsmouth
Hampshire
United Kingdom
PO6 3LY

# Sponsor information

**Organisation**
Birmingham & Black Country (University Hospital Birmingham NHS Foundation Trust)

**ROR**
https://ror.org/014ja3n03

# Funder(s)

**Funder type**
Government

### Funder Name
National Institute for Health Research

### Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 10/09/2020 | 15/09/2020 | Yes | No |
| Results article | | 25/08/2020 | 14/06/2023 | Yes | No |
| Basic results | | | 28/05/2020 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |