Local oestrogen treatment in postmenopausal women undergoing pelvic organ prolapse surgery

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
28/05/2015		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/05/2015	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
14/06/2023	Pregnancy and Childbirth			

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
Edgbaston
Birmingham
United Kingdom
B15 2TT

Additional identifiers

Clinical Trials Information System (CTIS)

2014-000179-18

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study design

Randomised; Interventional; Design type: Not specified, Treatment

Primary study design

Interventional

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

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes