

Local oestrogen treatment in postmenopausal women undergoing pelvic organ prolapse surgery

Submission date 28/05/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/05/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/06/2023	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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
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United Kingdom
B15 2TT

Additional identifiers

EudraCT/CTIS number

2014-000179-18

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Study design

Randomised; Interventional; Design type: Not specified, Treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/04/2015

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

Age group

Adult

Lower age limit

30 Years

Upper age limit

90 Years

Sex

Female

Target number of participants

Planned Sample Size: 100; UK Sample Size: 100; Description: Postmenopausal women with pelvic organ prolapse (Obs & Gynae)

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**

England

United Kingdom

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)

Sponsor details

Research and Development
Queen Elizabeth Hospital
Edgbaston
Birmingham
England
United Kingdom
B15 2TH

Sponsor type

Hospital/treatment centre

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

Publication and dissemination plan

This feasibility study is designed to identify if a substantive trial is possible, although the findings of this study may be of scientific interest to others in their own right. We plan the dissemination strategy in a number of ways: A report will be prepared for the funders and ethics committee. Findings will be more widely available via the trial study website. The feasibility findings will also be presented at local and national meetings such as the British Society of Urogynaecology or British Menopause Society. This will capture an extremely large audience of national and international clinicians. We will seek all opportunities to assess the willingness to participate throughout the feasibility study and gain research community support for in a substantive trial should such a RCT be proven feasible.

Intention to publish date

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?
Basic results	results		28/05/2020	No	No
Results article		10/09/2020	15/09/2020	Yes	No
Results article		25/08/2020	14/06/2023	Yes	No
HRA research summary			28/06/2023	No	No