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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
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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: Postmenapausal 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			28/05/2020	No	No
Results article	results	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