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Evaluating vaginal closure techniques during colporrhaphy and effects on post-operative pain

Submission date	Recruitment status	[X] Prospectively registered
04/01/2012	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/02/2012	Stopped	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/02/2016	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Pelvic organ prolapse is when the womb or vagina have lost normal support and drop down from the normal positions, causing women to feel a lump or heavy feeling. Gynaecologists frequently perform surgery for prolapse and this study is examining how the skin of the vagina is stitched together at the end of the operation. Our study will compare two different ways of closing the vaginal skin at the time of surgery and the effect on pain felt afterwards.

Who can participate?
Women over the age of 18 having surgery for prolapse in our hospitals are able to participate.

What does the study involve?
Participants will have their planned surgery as normal. The only thing which will be different if taking part in the study is the way in which the skin of vagina is closed at the end. The final step of any surgery is closure of the vaginal skin and this is where the way we close the skin will be different, depending on which group the participant been allocated to. One group will have the skin closed with separate stitches spaced about half a centimetre apart, and the other group will have a single, running stitch along the whole length of the surgical incision. We are interested in how much pain is experienced by participants, so at 24 hours after your surgery we will ask about your pain using a pain scale, scoring any pain felt from 0 to 10. This will be done again after 48 hours. Patients will be seen again 12 weeks after surgery to allow us to collect information on complications after surgery.

What are the possible benefits and risks of participating?
There are no short term benefits to participants directly although in the long term we expect our study will help future patients with pelvic organ prolapse because our results may show that less post-operative pain is experienced with one particular method over the other. There are no risks or disadvantages participating in this study as we are evaluating two different closure methods that are already in current surgical practice.

Where is the study run from?
The study is being run from the University of Leicester and patients having surgery in the University Hospitals of Leicester NHS Trust will be approached to take part.

When is the study starting and how long is it expected to run for?
The study will start in June 2012 and is expected to run for about 18 months

Who is funding the study?
The study is being funded by the University of Leicester and the UHL Trust

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1

Study information

Scientific Title
Prospective randomised trial evaluating vaginal closure techniques during colporrhaphy and effects on post-operative pain

Study objectives
Following vaginal prolapse surgery, post-operative pain is affected by the method of vaginal skin suturing. Our hypothesis is that continuous sutures cause less pain than interrupted sutures, without any difference in other operative morbidity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised prospective double-blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Uterovaginal prolapse

Interventions
Group 1: closure of the vaginal skin with interrupted polyglycolic acid sutures
Group 2: closure of the vaginal skin with continuous unlocked polyglycolic acid sutures

Intervention Type
Procedure/Surgery

Primary outcome measure
Post-operative pain immediately before pack removal, and 3 hours after pack removal. All packs will be removed 24 hours after surgery. Pain will be assessed by 10 point visual analogue scale score

Secondary outcome measures
1. Incidence of re-attendance for bleeding or discharge
2. Incidence of clinically diagnosed pelvic haematoma (attendance or admission with vaginal bleeding, ± fever, ± pain, ± ultrasound detection of haemotoma if clinically indicated)
3. Sexual dysfunction at 3 month follow-up Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12) for women who are sexually active
4. Prolapse stage (assesed by POPQ) of anterior and posterior compartment at 3 month follow up

Overall study start date

01/06/2012

Completion date
30/06/2013

Eligibility

Key inclusion criteria
Any patient undergoing anterior and/or posterior colporrhaphy and/or perineorrhaphy with or without vaginal hysterectomy

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
110

Key exclusion criteria
Patients receiving vaginal mesh repairs for prolapse, or concomitant surgical procedures such as mid-urethral tape, vault suspension procedures including sacrospinous ligament fixation and sacrocolpopexy, total abdominal hysterectomy

Date of first enrolment
01/06/2012

Date of final enrolment
30/06/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leicester Royal Infirmary
Leicester
United Kingdom
LE2 7LX

Sponsor information

Organisation
University of Leicester (UK)

Sponsor details
c/o Dr Graham Hewitt
Research Governance Manager
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Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
University/education

Funder Name
University of Leicester (UK)

Alternative Name(s)
UoL

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration