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Vault or uterine prolapse surgery evaluation: the VUE study

Submission date	Recruitment status	[X] Prospectively registered
18/10/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/10/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/06/2021	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims:
One in ten women will need an operation for prolapse. Prolapse occurs when the pelvic organs (such as the bladder, the bowel or the womb) come down into, or out of, the vagina. This is caused either by weakness of the tissues which usually support these organs or by weak pelvic floor muscles. It is most common in women who have had children, although there has been little research into its causes and treatment. Within the next 10 years, an extra 1 million women will reach the age when they are most likely to need prolapse surgery. This study will show which prolapse operations are the safest and most effective for all women. There are many different operations for prolapse: the VUE study only concerns women with a uterine (womb) prolapse or a vault prolapse (top of the vagina, in a woman who has had her womb removed previously). All the types of prolapse surgery in the VUE study are in common use in the NHS. The aim of this study is to answer one main question for each type of prolapse: that is, which of the operations gives the best results and is safest. Therefore, once we have the results of VUE, doctors in the future should be able to choose the prolapse surgery that has the best results with the fewest problems. This will mean fewer repeat operations, better health and quality of life for women, and better use of NHS facilities.

Who can participate?
Women who are going to have prolapse surgery for vault or uterine prolapse.

What does the study involve?
Women having surgery for uterine or vault prolapse will go into one of two trials:
1. Uterine trial: vaginal hysterectomy compared with an operation to suspend the uterus without removing it, and
2. Vault trial: suspending the vault from below (the vaginal route) compared with suspending it via the abdomen (tummy).
Women will not have to undergo any tests or procedures that are not part of routine care for prolapse. Women will have a routine physical examination before surgery and complete a questionnaire before their operation. The women will be examined and reviewed as outpatients at 12 months after surgery.

What are the possible benefits and risks of participating?
There may be no direct benefit to women who take part, but they will be helping with this research enabling doctors to assess which operation is best and safest.

Where is the study run from?
University of Aberdeen in collaboration with NHS Grampian

When is the study starting and how long is it expected to run for?
Recruitment will start in February 2013 and participants will be enrolled for 12 months. The study may extend beyond this as we intend to look at participants health with long term follow up.

Who is funding the study?
NHS National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre, Health Technology Assessment programme (NETSCC HTA).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
3/057/12

Study information

Scientific Title
Two parallel randomised controlled trials of surgical options for upper compartment (vault or uterine) pelvic organ prolapse

Acronym
VUE

Study objectives
The study is investigating which prolapse operations are the safest and most effective and cost-effective for women with vault or uterine pelvic organ prolapse

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. North of Scotland Research Ethics Service, 13/09/2012, ref: 12/NS/0093
2. Amendments submitted 10/10/2012

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vaginal wall prolapse

Interventions
Vault Trial
The two broad approaches to vault suspension are vaginal or abdominal.

Participants will be randomised to either
1. Vaginal vault suspension (Vaginal sacrospinous fixation (with sutures or mesh or a mesh kit)) OR
2. Abdominal vault suspension (Abdominal sacrocolpopexy (open abdominal or laparoscopic, with a mesh bridge))

Uterine Trial
The two options for uterine prolapse concern removal or retention of the uterus.

Participants will be randomised to either
1. Vaginal hysterectomy (Vaginal hysterectomy, with a vault suspension technique using sutures or mesh if necessary) OR
2. Uterine preservation (vaginal sacrospinous fixation of uterus with sutures or mesh, OR open abdominal or laparoscopic sacrohysteropexy with a mesh bridge)

At 12 months after surgery, all women will be examined for:
1. Clinical findings (prolapse stage using POP-Q)
2. Complications, e.g. mesh exposure.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. The primary clinical outcome is womens prolapse symptoms measured using the Pelvic Organ Prolapse Symptom Scale (POP-SS), at one year after surgery.
2. The primary quality of life outcome is the overall effect of prolapse symptoms on everyday life.
3. The primary economic outcome measure of cost effectiveness is incremental cost per QALY (QALYs based on the EQ-5D data).

All primary and secondary outcomes are measured at 6 and 12 months after surgery, measured in participant-completed questionnaires.

Key secondary outcome(s))
1. General
1.1. Immediate and late post-operative morbidity
1.2. Other adverse effects or complications
1.3. Operating time
1.4. Blood loss
1.5. Number of nights in hospital
1.6. Number of readmissions to hospital
1.7. Need for further surgery for prolapse or for urinary incontinence
1.8. Time to further surgery
1.9. Recommendation to a friend
1.10. Satisfaction with surgery

2. Prolapse outcomes
2.1. Subjective recurrence of prolapse
2.2. Subjective continuation / recurrence of prolapse symptoms
2.3. Subjective residual prolapse stage (POP-Q) at original site
2.4. Development of new (de novo) prolapse at another site
2.5. Need for other conservative prolapse treatment (e.g. PFMT, mechanical device)

3. Urinary outcomes
3.1. Urinary incontinence (persistent or de novo, and types of incontinence) using the ICI-Questionnaires
3.2. Voiding dysfunction
3.3. Need for alternative management for incontinence or voiding dysfunction (e.g. PFMT, mechanical devices, surgery, drugs, intermittent catheterisation)
4. Bowel outcomes
4.1. Constipation (persistent or de novo)
4.2. Faecal incontinence (persistent or de novo)

5. Sexual function outcomes
5.1. Dyspareunia / apareunia / difficulty with intercourse
5.2. Vaginal symptoms using the ICI-Vaginal Symptoms questionnaire

6. Quality of life outcome measures
6.1. Condition-specific quality of life measures
6.2. General health measures (EQ-5D)

7. Economic outcome measures
7.1. Cost and use of NHS services
7.2. Cost to the women and their families/carers;
7.3. QALYs estimated from the responses to the EQ-5D
7.4. The incremental costs, QALYs and incremental cost per QALY derived by the economic model over a longer term time horizon

All primary and secondary outcomes are measured at 6 and 12 months after surgery, measured in participant-completed questionnaires.

Completion date
28/02/2023

Eligibility

Key inclusion criteria
1. Women with vault or uterine prolapse requiring a surgical procedure
2. Women who are suitable for randomisation (gynaecologists view, i.e. not meeting exclusion criteria)
3. Women who are willing to be randomised (womans view)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
774

Key exclusion criteria
1. Potential future pregnancies
2. Co-morbidity necessitating particular approach, eg fibroids, previous abdominal surgery (scarring / adhesions)
3. Co-morbidity precluding randomisation (eg poor anaesthetic risk)
4. Obesity precluding abdominal approach (except if two vaginal approaches are feasible)
5. Colpocleisis (vaginal closure operation)
6. Women who are unwilling, unable or unsuitable to be randomized

Date of first enrolment

01/02/2013

Date of final enrolment
31/10/2016

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Aberdeen
Aberdeen
United Kingdom
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Sponsor information

Organisation
University of Aberdeen (UK)

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) - NIHR Health Technology Assessment Programme - HTA (UK) ref: 11/129/183

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	01/03/2020	10/03/2020	Yes	No
Protocol article	protocol	08/09/2016		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes