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Comparing the complications between open and keyhole hysterectomy

Submission date
25/06/2020

Recruitment status
Stopped

Registration date
22/07/2020

Overall study status
Stopped

Last Edited
06/06/2025

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study will compare the severity and rate of complications experienced by women who are having a hysterectomy for a benign condition by either an open (cut in the abdomen) or through a keyhole (laparoscopic) route. The side effects from cutting open the abdomen such as infection and pain have meant that women having an open hysterectomy need to stay in hospital longer than women having keyhole surgery. Women having their hysterectomy through an open cut often take longer to recover compared with women who've had their operations via the keyhole route. Many people believe that keyhole surgery takes longer to do than an open operation and the surgeon needs to be a specialist to do the keyhole operation. Low-quality evidence suggested that women who have their wombs removed via the keyhole route may have more bladder and waterworks problems than women who've had their operation via the traditional open route. However, since these studies were done the surgical equipment used for keyhole surgery has got better and more surgeons have done more keyhole techniques during their training and once they specialise. As such an open route may not be better than a keyhole route any longer. This study will look at complications experienced by women who have their wombs removed by either an open or keyhole route, as well as looking how long they take to recover. It will look at the longer term outcomes of the procedures to see how women feel about their lives up to 15 months, as well as if the woman needed to go back for further treatment after her operation.

Who can participate?
Women who are at least 16 years of age who have a benign gynaecological condition requiring a hysterectomy

What does the study involve?
Participants will be randomly allocated to undergo their hysterectomy by either a laparoscopic or open abdominal route. Before their operation, women who agree to take part in the study will fill in some questionnaires that will measure their quality of life, bladder and bowel function, as well as selecting some usual activity criteria they feel that they should attain for them to consider themselves recovered post-surgery. After the operation, the amount of pain experienced by the women and her analgesic (painkiller) use will be recorded as will the time to reaching the individually selected recovery criteria. Also recorded will be the generic quality of

life reported by the woman and the time to return to work (if working) and work participation. A questionnaire will record the woman's satisfaction, bladder and bowel function, and any new gynaecological symptoms (such as pelvic organ prolapse) are experienced. The woman will be asked to share with us how she feels about her body image, her sexual function, as well as any contact with they may have had with Community & Clinical Care Services i.e. outpatients or emergency visits, re-presentations re-admissions to hospital.

What are the possible benefits and risks of participating?
As the procedures under study are both routine there may be no immediate additional benefit to the participant, but the information provided will help in the long term to improve the surgical outcomes, such as optimising safety and speed of recovery, for women who need to have a hysterectomy in the future. All surgical procedures have some element of risk associated with them, but as the woman will have already been referred for a hysterectomy and will likely be undergoing the procedure in the near future, taking part in this study is not associated with any additional risk.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
January 2019 to April 2025

Who is funding the study?
National Institute for Health Research Health Technology Assessment (NIHR HTA) (UK)

Who is the main contact?
The LAVA trial office
LAVA@trials.bham.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
287988

National Institute for Health and Care Research (NIHR)
128991

Protocol serial number
HTA -

Study information

Scientific Title
LAparoscopic Versus Abdominal hysterectomy (LAVA) trial

Acronym
LAVA

Study objectives
To determine the clinical and cost-effectiveness of laparoscopic hysterectomy compared to open abdominal hysterectomy for women with a benign gynaecological condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/02/2021, West Midlands – Edgbaston REC (3rd Floor, Barlow House, Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8070, +44 (0)207 104 8019; edgbaston.rec@hra.nhs.uk), ref: 21/WM/0019

Primary study design
Interventional

Study design
Parallel open multicentre randomized controlled trial with integrated health economic evaluation and an internal pilot with an embedded qualitative process evaluation

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Benign gynaecological conditions requiring a hysterectomy

Interventions
Before their operation, women who agree to take part in the LAVA study will fill in some questionnaires that will measure their quality of life, bladder and bowel function, as well as selecting some usual activity criteria they feel that they should attain for them to consider themselves recovered post-surgery.

Randomisation will be provided by a secure online randomisation system at Birmingham Clinical Trials Unit (BCTU). After participant eligibility has been confirmed and informed consent has been received, the participant can be randomised into the trial. Randomisation Notepads will be provided to investigators and may be used to collate the necessary information prior to randomisation.

Participants will be randomised at the level of the individual in a 1:1 ratio to undergo their hysterectomy by either a laparoscopic or open abdominal route.

A minimisation algorithm will be used within the online randomisation system to ensure balance in the treatment allocation over the following variables:
1. Previous caesarean section (yes/no)
2. BMI (<29.9, 30-34.9, >/=35 kg/m²)
3. Uterine Size - <=12 weeks, >12 weeks
4. Planned retention of cervix (yes/no)
5. Recruitment centre
6. Planned retention of ovaries
A 'random element' will be included in the minimisation algorithm, so that each patient has a probability (unspecified here), of being randomised to the opposite treatment that they would have otherwise received. Following randomisation, a confirmatory e-mail will be sent to the randomiser, the local PI and the trial co-ordinator, with the participant's unique trial number.

After their operation the amount of pain experienced by the women and her analgesic use will be recorded as will the time to reaching the individually selected recovery criteria. Also recorded will be the generic quality of life reported by the woman and the time to return to work (if working) and work participation.

A questionnaire will record the woman's satisfaction, bladder and bowel function, and any new gynaecological symptoms (such as pelvic organ prolapse) are experienced.

The woman will be asked to share how she feels about her body image her sexual function as well as any contact with they may have had with Community & Clinical Care Services i.e. outpatients or emergency visits, re-presentations/re-admissions to hospital.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Major surgical complications defined as Clavien-Dindo grade III-V, including pulmonary embolus, blood transfusion or adverse anaesthetic event up to and including 6 weeks post-surgery

Key secondary outcome(s)
1. Time to full physical recovery (resumption of usual activities) measured using Patient-Reported Outcomes Measurement Information System Physical Function (PROMIS-PF) item bank v1.2. The participant will record the date when each of her eight pre-selected physical activities is achieved using a text application. Weekly text reminders will be sent to complete the PROMIS-PF during the first 6 weeks, fortnightly from 6 to 12 weeks and three weekly up to 54 weeks. Once all eight activities are achieved text reminders will stop.
2. In-hospital postoperative pain reported by the participant up to (and including) the day of discharge
3. In-hospital postoperative analgesia use reported by the medical or nursing staff up to (and including) the day of discharge
4. Quality of recovery measured using Quality of Recovery 15 (QoR-15) completed by the participant before their discharge from the hospital
5. Time to discharge calculated from the admission and discharge information provided by the clinical staff on CRFs after discharge
6. Post-operative pain and analgesia use measured using the numerical rating scale (NRS) post-

operatively and at time of discharge
7. Generic quality of life measured using EuroQol-5D-5L and VAS at 6 and 12 weeks post-surgery and again at 15 months post-randomisation. These outcomes will be collected also at 27 and 39 months post-randomisation for subgroups of participants reaching these timepoints prior to the close of the study
8. Time to return to work (if working) and work participation measured using the Work Productivity and Activity Impairment Questionnaire (WPAI–GH) at 12 weeks post-surgery
9. Bladder function measured using the Urogenital Distress Inventory (UDI) at 15 months post-randomisation. These outcomes will be collected also at 27 and 39 months post-randomisation for subgroups of participants reaching these timepoints prior to the close of the study
10. Bowel function measured using the Defecatory Distress Inventory (DDI) at 15 months post-randomisation. These outcomes will be collected also at 27 and 39 months post-randomisation for subgroups of participants reaching these timepoints prior to the close of the study
11. New gynaecological symptoms assessed using the Pelvic Organ Prolapse Quantifications [POPQ] at 15 months post-randomisation. These outcomes will be collected also at 27 and 39 months post-randomisation for subgroups of participants reaching these timepoints prior to the close of the study
12. Body image assessed using the Body Image Scale (BIS) at 15 months post-randomisation. These outcomes will be collected also at 27 and 39 months post-randomisation for subgroups of participants reaching these timepoints prior to the close of the study
13. Sexual function assessed using the Sexual Activity Questionnaire (SAQ) at 15 months post-randomisation. These outcomes will be collected also at 27 and 39 months post-randomisation for subgroups of participants reaching these timepoints prior to the close of the study
14. Subsequent treatment, contact with community and clinical care services i.e. outpatients or emergency visits, re-presentations/re-admissions to hospital, time away from normal activities collected on a follow-up questionnaire at 6 and 12 weeks post-surgery and again at 15 months post-randomisation. These outcomes will be collected also at 27 and 39 months post-randomisation for subgroups of participants reaching these timepoints prior to the close of the study

Completion date
01/04/2025

Eligibility

Key inclusion criteria
1. Women aged at least 16 years of age or over and able to give informed consent to participate
2. Has a benign gynaecological condition that is being treated with a hysterectomy
3. This hysterectomy can be undertaken by either a laparoscopic or open abdominal route

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 Years

Sex
Female

Total final enrolment
75

Key exclusion criteria
1. Women with suspected malignant disease of the genital tract
2. Women who require concomitant gynaecological surgery, or bladder or other pelvic support
3. Women who require excision of endometriosis requiring dissection of the pararectal space

Date of first enrolment
01/04/2021

Date of final enrolment
01/01/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Birmingham Women's Hospital
Mindelsohn Way
Birmingham
United Kingdom
B15 2TG

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

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
Consent will be sought for study participants for their anonymised data/datasets generated during and/or analysed during the current study to be shared with external researchers following publication of the results in a peer-reviewed journal. These datasets will be available upon approval from the LAVA trial management group and the BCTU data sharing committee in line with standard data sharing practices for clinical trial datasets.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/06/2025	06/06/2025	Yes	No
Protocol article		05/09/2023	06/09/2023	Yes	No
HRA research summary			26/07/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes