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# LAparoscopic Versus Abdominal hysterectomy (LAVA)

**Version 3.0– 26th May 2021**

# Participant Information Sheet

We would like to invite you to take part in the LAVA trial. This is a research study looking at the advantages and disadvantages of two ways of doing a hysterectomy; either by an abdominal (open) route, or by a laparoscopic (keyhole) route. We are especially interested in understanding the relative risk of complications and speed of recovery associated with each type of hysterectomy. It is important that you understand why this research is being done and what it will mean for you if you decide to take part. A member of our team will go through the study with you and answer any questions that you might have. Please take your time to read the information carefully, and ask any questions, so that you can make an informed choice about taking part in the LAVA trial.

If you have any questions or would like any further information then please contact about the LAVA trial any of the following:

Local PI: <Insert contact name>

Local PI email: <insert contact email>

Local Research Nurse: <Insert contact name>

Local Research Nurse email: <insert contact email>

Trial Manager email: LAVA@trials.bham.ac.uk

Support and confidential advice can also be found through your hospital's NHS Patient Advisory Liaison Service (PALS) or equivalent:

Telephone: <Insert local PALS contact numbers> Email: <Insert local PALS email address>

## Brief background and purpose of this study

A hysterectomy is a common surgical procedure which involves removing the womb (uterus) for a variety of reasons. The majority of women who have a hysterectomy do so because of benign (i.e. non-cancerous) problems which can include things like heavy periods or pain and discomfort.

The traditional method of having a hysterectomy is through a procedure called an abdominal (open) hysterectomy. This usually involves the surgeon making either a horizontal cut (incision) across the 'bikini line' or a vertical incision from the bikini line to just underneath the belly button. A laparoscopic (keyhole) hysterectomy is a type of 'key-hole' surgery that avoids making large cuts. The procedure involves making a small usually about 1cm cut in the belly button which allows a small camera to be inserted into the body. Two to four additional small cuts of 0.5cm to 1cm are then made to insert the equipment needed to carry out the operation.

The aim of this trial is to compare the safety, recovery and quality of life after open or keyhole hysterectomy. The study will also evaluate the relative cost-effectiveness of the types of hysterectomy.

## Why have I been asked to take part?

Your hospital team have found that you can take part in this study if you want to. This means that you have a benign condition that requires a hysterectomy and you are suitable for both open or keyhole surgery. We would like you to help us to understand what the best surgical procedure is for women who will need a hysterectomy in the future.

## Do I have to take part?

No. Taking part in this study is **voluntary** so it is up to you if you want to take part or not. If you don't want to take part you do not have to give us a reason why. Please rest assured that no matter what you decide, your health care team will always work in your best interests and the quality of your care will not be affected in any way.

## What would taking part in the study involve?

There are a few different phases of this study and each of them will give us important information that we need to do to understand which type of hysterectomy is best for women with benign conditions. When designing this study, we were very careful to make sure that participating will not take up too much of your time.

<u>Before your operation</u>

If you decide to take part after reading this information sheet, the first thing that you will need to do is complete a consent form confirming that you have understood the study and that you are happy to take part. Your local hospital will collect some information about you

from your medical notes for the study. This will include your name, home address, date of birth, telephone number, ethnicity, Body Mass Index (BMI), if you have had any caesarean sections, the size of your womb and other relevant details of your medical history including your hysterectomy.

You will be asked to fill in some questionnaires that tell us about your health and life now, as well as any relevant pelvic symptoms relating to bowel, urinary and sexual function. Some of the questionnaires will cover quite personal topics, if you have any concerns answering these questions please feel free to discuss this with your hospital research team. You will also be asked to choose eight recovery targets or 'goals' that are important to you in order to determine when you are fully recovered from your operation.

Once you have done this your information will be entered into a secure online database at the University of Birmingham and you will randomly be assigned to have either an open or keyhole hysterectomy. Please note, that neither you nor the clinical team has any control over the type of procedure that you will be randomly assigned to so if you have a preference as to which type of surgery you want you can't take part in this study.

<u>After your operation and still in hospital</u>

The day after your operation we will ask you to fill in a questionnaire telling us how you feel about your recovery. Each day after your operation that you are still in hospital we will ask you to complete a short questionnaire telling us how much pain you think you are in.

<u>After your operation and back at home</u>

For the first two weeks, we will give you a daily diary to complete. This diary will let us know about any pain and discomfort you may have as well as any medication that you have taken during this time.

<u>At six weeks after your operation</u>

We will ask you to complete a written questionnaire that will let us know of any health problems you may have had since your operation and your use of any hospital or community health services. We will also ask about how you feel about the quality of your life.

<u>At 12 weeks after your operation</u>

We will ask you to complete a written questionnaire that will enquire about the impact of surgery on your ability to work and how you feel about the quality of your life.

<u>For the first six months</u>

We will contact you every week during the first 3 months after your operation, and then fortnightly up until 6 months, to ask you about your recovery targets. Contact will stop once you have reached all your recovery targets. Depending on what you prefer we will do this by text message, email, telephone, or voice over internet protocol (VOIP e.g. Facetime or Skype).

If you want to be contacted by text to email then we will send you a link to complete your questionnaire online.

If you want to be contacted by text to do this we will need to send your mobile telephone number and study number to an external company (Textlocal) who will send you text messages containing the link to the online questionnaire asking you how many of the recovery targets you set before your operation you have been reached. Textlocal will only be given your study number and mobile telephone number. Textlocal will not be given your name, address, or any other information about you.

Your study number, and telephone number will be encrypted whilst being stored by Textlocal and your data will not be used by them for any other purpose. Once the study is finished, Textlocal will securely delete all of your data that they hold.

12 months after your operation

We would like you to complete a final in-depth questionnaire. Some of the questions will be similar to those that you answered previously, but we will also ask some additional questions about things like satisfaction with your surgery, any new symptoms and how you feel your body image.

Throughout your time as a trial participant, the clinical team will provide us with some standard information from your medical notes, this will be completed by the doctors and nurses involved in the study so you will not have to do anything.

The data listed above (at 12 months after your operation) will also be requested at 24 and 36 months after your operation

We will invite some women to complete this same questionnaire at 24 months and 36 months after hysterectomy so we can get information about longer term effects. If you do not have your operation, we will not follow you up.

## Are there any benefits for me taking part in the study?

This study will help us to determine the best surgical procedure for women who need to have a hysterectomy. Whilst there may be no immediate benefit to you, the information that you provide to us 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.

## Are there any risks in taking part?

All surgical procedures have some element of risk associated with them, however as you 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.

## Can I speak to my GP?

Yes, and with your permission, your GP practice will be notified about your participation in the LAVA trial. They will be given details about how they access more information about the study, so feel free to discuss your participation with your GP. Please note that your GP will not be able to access any of the answers that you provide to us or access any of information that we hold on file about you, this is because we take data protection very seriously.

## Who is organising and funding this research?

This important research is being funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (reference number: NIHR128991). This is UK government's largest funder of healthcare research. This study is sponsored by the University of Birmingham who have reviewed the research plans and have accepted legal and ethical responsibilities for the study (reference number: RG_19-156). The research will be run by the University of Birmingham Clinical Trials Unit (BCTU) which is a specialist department that plans, organises and conducts clinical trials such as LAVA.

## Has this study been reviewed and approved?

Any research that is conducted within the NHS has to follow the strict guidelines and regulations that are in place to ensure patient safety. The research ethics committee (REC) are an independent group that have approved this study after ensuring that your safety, rights, well-being and dignity will not be compromised if you decide to take part. In addition, the research & development (R&D) department of each hospital involved in this study has reviewed the LAVA trial and have approved it to be carried out within their hospital.

## Have any patients or members of the public been involved in this study?

When designing this study, it was important for us to ensure that the comments and suggestions of the public taken on board so that we could ensure that that this study was suitable for women who have just had a hysterectomy. Therefore, our research was developed with the help of the Royal College of Obstetricians and Gynaecologists (RCOG) Women's Voices Group, the Hysterectomy Association and the Birmingham Women's Hospital Hysterectomy Focus Group. We also set up a Patient and Public Involvement (PPI) survey which was completed by 945 women. Taken together, all of this feedback was considered when designing the study. Representatives of women who have had a hysterectomy are involved in the group who oversee the management of the LAVA study.

## What personal information will you be collecting?

In order to carry out this research project we will need to collect information about you and some of this information will be personal data. Under the data protection law, we have to provide you with very specific information about what we do with your data and about your rights. We have set out below the key information you need to know about how we will use your personal data.

More information on how the University of Birmingham processes personal data can be found on the University's website on the page called 'Data Protection - How the University Uses Your Data' (https:// www.birmingham.ac.uk/privacy/index.aspx).

**Who is the Data Controller?**

The University of Birmingham, Edgbaston, Birmingham B15 2TT is the data controller for the personal data that we process in relation to you.

**What data are we processing and for what purpose will we use it?**

We will collect and process your personal data to conduct the research project as explained in this Participant Information Sheet.

**What is our legal basis for processing your data?**

The legal justification we have under data protection law for processing your data is that the sponsor is undertaking medical research in the public interest. We do not envisage any problems occurring as a result of your participation in the study. However, all patients are covered for negligent harm according to NHS indemnity guidelines. If you have a concern about any aspect of this study, you should ask to speak to a member of the research team who will do their best to answer your questions (our contact details are on the front cover of this information leaflet).

**How will we use information about you?**

We will need to use information from you and your medical records for this research project.

This information will include your name, NHS number and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**Who will my personal data be shared with?**

The personal data that we will collect about you will include your name, contact details, date of birth, and NHS number. The only people who will see this information is a very small number of the study team at the University of Birmingham who are directly managing the LAVA study, and the people at the University of Birmingham, and other regulatory bodies who make sure that the research is being done properly.

Your name and contact details will only be provided to the study team when essential, in most cases you will be identified by a unique participant identification number and your partial date of birth.

We will keep the identifiable information about you that is collected from this study for a minimum of 10 years after the study has finished. The identifiable data we are hold on you will not be shared with any third party during this storage period.

Sometimes, external organisations assist us with processing your information, for example, in providing text reminder services. These organisations act on our behalf in accordance with our instructions and do not process your data for any purpose over and above what we have asked them to do. These companies will not store any of your data or responses after the study has finished. We make sure we have appropriate contracts in place with them to protect and safeguard your data.

When you agree to take part in a research study, the anonymised information about your health and care may be provided to researchers who may be based in universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information we share will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

**How will my personal data be kept secure?**

The University of Birmingham ensures that personal data is handled, stored and disposed of confidentially and securely. Staff receive regular data protection training, and the University has put in place organisational and technical measures so that personal data is processed in accordance with the data protection principles set out in data protection law.

**How long will my personal data be kept?**

Your data will be retained for a minimum of 10 years after the publication of the research outcomes. If you withdraw from the project, we will keep the information we have already obtained but, to safeguard your rights, we will collect the minimum of information that personally identifies you.

**Your rights in relation to your data**

You may have the following rights in respect of your personal data:

- The right to access your data (often referred to as a Subject Access Request).
- The right to rectification of inaccuracies in your data.
- The right to erasure your data (in certain circumstances).
- The right to restrict processing of your data (in certain circumstances).
- The right to object to the processing of your data (in certain circumstances).
- The right to ask for your personal data to be transferred electronically to a third party.
- The right to withdraw consent.

However, your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the project, we will keep the information we have already obtained but, to safeguard your rights, we will use the minimum personally-identifiable information possible.

You can withdraw your consent to our processing of your data at any time. We will store the information about you that we have already obtained if this has already been analysed, but we will clarify with you whether we can use your stored data, if at all, for any new analysis, whether we can collect any new data from your medical notes, and whether we can link your stored data to other NHS or central government bodies.

In the unlikely event that you lose the capacity to consent during the study you will be withdrawn, and we will use any data already collected.

Should you wish to withdraw from the study, but do not let the study staff or study office know of the type of withdrawal you want, then we will assume that you are happy for us to continue using the data we have collected on you , as well as linking your information with any NHS or central government bodies for measuring any long-term outcomes. We will also assume that you do not want the study office to contact you in the future.

If you decide to withdraw and let us know that you do not want us to use your data then no new analysis will be started using your information. However, we cannot remove your data from any analysis that was completed prior to your withdrawal from the trial.

Under the provisions of the General Data Protection Regulation (GDPR) 2018, you have the right to know what information the Trials Office has recorded about you. If you wish to view this information, or find more about how we use this information, please contact Legal Services at the address below. Please note that a small fee may be payable to retrieve this information.

If you would like more information on your rights, would like to exercise any right or have any queries relating to our processing of your personal data, or if you wish to make a complaint about how your data is being or has been processed, please contact:

The Information Compliance Manager, Legal Services, The University of Birmingham, Edgbaston, Birmingham B15 2TT
Email: dataprotection@contacts.bham.ac.uk
Telephone: +44 (0)121 414 3916

**What will you do with the results of the research study?**

The results of the LAVA trial will be made available in specialist medical journals and presented at conferences, and in publicly available websites. This will help doctors, patients and key decision makers within the NHS to get a better understanding of which type of hysterectomy is better for women who will need this operation in the future. If we do publish the results of this study, please rest assured that any information relating to you will be completely anonymous and there will be no way that you can be identified. If you would like to know the final results of this study, please let a member of the research team know and we will be more than happy to provide you with a summary of the research once it has finished.

**Do you have any further questions?**

Please take the time to decide whether you wish to take part in the LAVA Study. Please feel free to discuss this invitation to join the LAVA study with your friends, relatives, or anybody else that you want to.

Having read this information sheet, we hope that you will choose to take part in the LAVA Study. If you have any questions about the study now or later, feel free to ask your medical team, or the person who is responsible for the LAVA Study at your hospital. Their name and telephone number are shown at the start of this document. Only the clinical staff looking after you can give you advice about your medical care and the treatment options that may be available to you.

If you require any general information about research, the UK Clinical Research Collaboration has produced a useful guide entitled, 'Understanding Clinical Studies'. This can be downloaded from their website: www.ukcrn.org.uk. If you require specific information about the research project, please either contact any of the LAVA staff listed at the start of the document or visit our website: www.birmingham.ac.uk/LAVA