PATIENT INFORMATION LEAFLET

For patients undergoing surgery to repair UTERINE or VAULT prolapse

Please take time to read this information leaflet. Discuss it with your family, friends or your GP if you wish. You can also contact us at any time if there is anything you do not understand or if you would like more information.

Contents

Version 4: 01 October 2013

1. What is VUE?

VUE is a research study looking at different types of surgery for women with either a prolapse of the womb (uterus) or a prolapse of the top of the vagina (vault), in women who have had the uterus removed (hysterectomy). It is being carried out to establish the best way of treating these conditions. The study will run for three years and will recruit around 800 women from hospitals all over the United Kingdom.

2. Why have I been invited to take part?

You are being invited to take part because you will soon be having an operation for your vault or uterine prolapse. Before you decide, it is important that you understand why the research is being done and what it will involve.

3. Background

Prolapse is a common condition and as many as one in ten women will have an operation to correct it at some time in their lives.

At the present time, surgeons in the NHS are successfully using several different operations to repair vault or uterine prolapse. VUE aims to compare the results of these different operations over a long period to find out which are the most successful.

By joining the study, you will help us do that. You will find more information about the operations in the Surgical Information Sheet, and your gynaecologist will also discuss them.

4. What is the purpose of the study?

The aim of the study is to establish which of the various prolapse operations is most successful. The results will help doctors choose the surgery that has the best and safest results with the fewest problems. This will mean fewer operations being repeated, better health outcomes and quality of life for women, and a better use of NHS facilities.

5. What will taking part mean for me?

Your surgery will be carried out in line with normal practice. You will not have to undergo any tests or procedures that are not part of routine care for prolapse.

There will be no extra benefit to you if you do take part in the study but by doing so you will be helping this important research so as to enable doctors to assess which operation is best and safest for women in the future.

6. Do I have to take part?

No, that is your decision. Even if you do agree to take part you can withdraw at any time without giving a reason. Your decision will not affect your current or any future medical treatment.

Before you decide, your gynaecologist or the VUE Recruitment Officer will provide you with more information and will be happy to discuss any questions you may have.
Then, if you agree to take part, you will be asked to sign a form giving your consent to be included in the study.

Your gynaecologist will discuss all the relevant issues surrounding the surgery itself, and you will sign a separate NHS information and consent form for your operation.

7. What does taking part involve?

There are different types of operations that you could have for your prolapse. If your gynaecologist thinks that all of them would be equally suitable for you, with your agreement, you will be randomly allocated to a particular type of operation.

If you do not wish to be randomised, or if your gynaecologist decides that one particular operation is best for you, you will not be included in the study.

If you decide to take part, the following diagram shows you what you will be asked to do:

Before your operation

- You will be asked to complete a questionnaire about the problems caused by your prolapse and how it affects your life
- As part of your routine care you will have a vaginal examination to find out what type of prolapse you have and to measure its extent.

After your operation

- At both 6 and 12 months you will be sent a further questionnaire to fill in and return to the VUE team.

Later

- 12 months after your operation, you will be examined in your gynaecology outpatients' clinic to check your progress.
- We will ask for your permission to follow you up in the longer term, to see how things are going.

Each questionnaire will take about 10-20 minutes to complete. Your answers will help us measure how things have changed after the operation. It is therefore important that you return these if possible. Although we would like you to complete the questionnaires fully, you do not have to answer every question if you don't want to.

Contacting you again in the future, perhaps by asking you to fill in another questionnaire, will help us learn more about your long term health and how your surgery has affected you, for instance, by asking you to fill in another questionnaire. We might also ask you to take part in other similar studies.

However, you will not have to reply to any questionnaires or take part in other studies unless you want to at that time.

8. Will the information I provide be kept confidential?

Yes, all information collected for the study at any time, will be stored using a Study Identity Number for confidentiality and will be kept secure using passwords. This includes any questionnaires that may be sent to you in the future, as mentioned in Paragraph 7. The information will only be available to the research team and the NHS or University bodies responsible for maintaining research standards. Your own doctor (GP) will be told that you are taking part in the study, and your gynaecologist will also let him know how you are after your examination at 12 months, as normal practice.

We hope to link your answers with electronic data from your NHS medical records related to your health after prolapse surgery. This will increase the usefulness of the whole study. We will ask you for specific consent to do this and again, this information will be kept secure and confidential.

9. How will the information I provide be used?

When the study is complete, gynaecologists will be informed of its recommendations so that in future all women can receive the best and safest operations. The results of the study will be published in scientific journals and a short version will also be available to those women who took part in the study if they wish. Those wishing to see the full results will be provided with links to let them do so. No woman will be identifiable in any of the study reports.

10. What if there is a problem?

We do not expect any harm to come to you by taking part in this study. While all operations carry a degree of risk, all the techniques and materials used in the study are already being employed in the NHS for prolapse surgery. Your participation is only to help us evaluate these procedures and should not involve any **additional** risk.

Your normal legal rights will not be affected. If you wish to complain about your health care or any aspects of this study, the normal NHS mechanisms will be available to you. If you have private medical insurance, please check with your insurers before agreeing to take part in the study.

If you have a concern about any aspect of the study, you can ask to speak with the research team who will do their best to answer your questions (phone 01224 438194). If you are still concerned and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your hospital.

If you became unable or unwilling to continue in VUE, we would withdraw you from the study. We would ask to retain, confidentially, the relevant information that we had already

collected about you, for the purposes of this study only. However, you may withdraw all the information you have provided.

11. Who is doing this study?

This study is being funded by the NHS National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre, Health Technology Assessment programme (NETSCC HTA). The research is being carried out by a group of experienced doctors and researchers from the Health Services Research Unit at the University of Aberdeen in collaboration with the British Society of Urogynaecologists, which is part of the Royal College of Obstetricians and Gynaecologists.

12. Who has approved it?

North of Scotland Research Ethics Committee, your local hospital and your gynaecological consultant have given approval for this study to be carried out. An independent Steering Committee and a Data Monitoring Committee monitor safety and ensure that the study is conducted in accordance with good research practice.

13. How do I get in touch with the research team if I want any further information?

If you have any questions about the study, or any aspect of your treatment or health, please speak to your VUE recruitment officer or your own gynaecology consultant or GP. Alternatively you can contact the VUE Study Office (details over).

SPACE FOR LOCAL CONSULTANT /
RECRUITIMENT OFFICER DETAILS
(box for sticky label)

You can contact the study team who are organising the research:

Lynda Constable, Trial Manager
VUE STUDY OFFICE
Tel. 01224 438194

Or, the Chief Investigator

Professor Cathryn Glazener
Health Services Research Unit
University of Aberdeen
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Or you can email us at:

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Thank you for reading this leaflet and considering taking part in VUE.