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

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or the Chief Investigator
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Thank you for reading this and considering taking part in this study.

PROSPECT
PROLAPSE SURGERY: PRAGMATIC EVALUATION AND RANDOMISED CONTROLLED TRIALS

PATIENT INFORMATION LEAFLET

The purpose of the PROSPECT research study is to compare the results of different types of surgery for women with vaginal wall prolapse, in order to identify the most effective and efficient operation.

Please take time to read this information leaflet and discuss it with your family, friends or GP if you wish.

Do not hesitate to contact us if there is anything you do not understand or if you would like more information.

Version 3: 01 April 2010

1. Description of Study

There are many different operations for prolapse, depending on the type of prolapse women have and whether it is the first or a subsequent prolapse operation. Types of prolapse include the front wall of the vagina [an anterior prolapse] and/or a prolapse to the back wall [a posterior prolapse]. There is not enough evidence from previous research to let us know which operations should be used.

2. Why have I been invited to take part?

You are being invited to take part in the PROSPECT study because you will be having an operation for your vaginal prolapse. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

3. Background

One in ten women will need an operation for prolapse. All the types of prolapse surgery that you might undergo in this study are in common use in the NHS.

There are several different prolapse operations currently being used successfully in the NHS, some of which include the use of mesh or graft materials. Mesh is thought to provide extra support for the prolapse while it is healing, thus possibly reducing the chance of failure. On this basis, some doctors are already using mesh in their prolapse surgery. We do not know, however, whether there are more complications with mesh compared with operations without mesh. We need to be able to evaluate these different operations, particularly in the long term, and your participation in the study will help us do so.

If you became unable or unwilling to continue in PROSPECT, we would withdraw you from the study. We would retain, confidentially, the relevant information that we had already collected about you for the purposes of the study only.

10. 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.

11. Who has approved this study?

Committee Two of the North of Scotland Research Ethics Service, 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 will monitor safety and ensure that the study is conducted in accordance with good research practice.

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

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

8. How will the information I provide be used?

We hope that over 4000 women will take part in this study during the next three years in centres across the UK. Gynaecologists will be informed of the recommendations from the study, 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. Women will not be identifiable in any of the study reports.

9. What if there is a problem?

We do not expect any harm to come to you by taking part in this study. All the materials and techniques are already being used in the NHS for prolapse surgery. Your participation in the study is therefore only to help us evaluate these procedures and should not involve any additional risk to you.

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

Taking part in this study does not affect your normal legal rights. Whether or not you do take part, you will retain the same legal rights as any other patient in the NHS (which include professional indemnity insurance for negligence). If you wish to complain about your health care or any aspects of this study, the normal NHS mechanisms will be available to you. Although we do not expect participation to affect private medical insurance, please check with your insurers before agreeing to take part in the study.

You will not have to undergo any tests or procedures that are not part of routine care for prolapse.

There may be no direct benefit to you if you do take part, but you will be helping with important research enabling doctors to assess which operation is best and safest.

4. What is the purpose of the study?

The aim of the study is to answer two main questions: (1) which of the operations gives the best results and is safest, and (2) whether or not the use of mesh improves women's prolapse symptoms without causing extra problems. Therefore, once we have the results of PROSPECT, 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.

5. Do I have to take part?

It is up to you whether you decide to take part. If you do take part you would be free to withdraw at any time without giving any reason. This will not affect your current or future medical treatment. Before you decide, your gynaecologist or the PROSPECT Recruitment Officer will provide you with more information and will be happy to discuss any questions you may have. If you agree to take part, you will be asked to sign a consent form for this research study. Your gynaecologist will make you aware of all relevant issues surrounding the surgery itself, and you will sign a separate NHS information and consent form for your operation.

6. What will participation in the study involve?

As described above, there are different types of operations that you could have. If your gynaecologist thinks that all of the operations would be equally suitable for you, with your agreement you will be allocated at random to one particular type of operation. Therefore you would be put into one group by chance (randomly) and all of the women in that group will be given the same operation.

If you decide that you do not wish to be randomised, or your gynaecologist decides that a particular operation is best for you, you will be allocated to that group (type of surgery). You will still be part of the study. Your gynaecologist will discuss all of this with you.

The following diagram shows you what you will be asked to do:

Before your operation

- You will be asked to complete a booklet of questions about the problems caused by your prolapse and how this 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 size

⇩

After your operation

- At 6, 12 and 24 months you will be sent a questionnaire to fill in and return to the PROSPECT team

⇩

Randomly allocated women only

- At 12 months you will be examined in gynaecology outpatients to check your operation was successful
- At 18 months you will be sent an extra questionnaire to fill in and return to the PROSPECT team

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

With your permission, we would like to contact you again in the future to check on a) your long term health, for example by sending you other questionnaires to add information to what we already know about you, and b) to ask you to take part in other relevant studies. However, you will not have to reply to any questionnaires or take part in other studies unless you want to at that time.

7. 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 the questionnaires that may be sent to you in the longer term as mentioned above. 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 informed of your participation in the study.

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