THANK YOU
for reading this

You have been given this information by:

(name)

on

(date)

If you have any queries at the moment, please contact a member of the research team at the University of Aberdeen, telephone: [redacted] or email: [redacted].

Alternatively, you may contact your own gynaecologist.

PROSPECT
PROLAPSE SURGERY: PRAGMATIC EVALUATION AND RANDOMISED CONTROLLED TRIALS

STUDY FLYER

Short summary for women having prolapse surgery

Version 4: 01 March 2011

What is PROSPECT?

PROSPECT is a clinical research study that is being run in your hospital in association with researchers throughout the UK. PROSPECT is funded by the NHS Health Technology Assessment Programme and is centrally co-ordinated at the Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit, University of Aberdeen.

Why have I been invited to take part in PROSPECT?

You have been invited because you will be having surgery for your prolapse in the near future. We want to give you some brief information about the study now, to give you plenty time to think about it before your operation.

What is the purpose of the study?

There are several different types of prolapse operations currently being used in the NHS, some of which include the use of mesh materials.

However we do not know which type of operation is best and whether using mesh improves prolapse symptoms without causing any extra problems.

If your gynaecologist thinks that any of the types of surgery are equally suitable for you, and you agree, you will be randomly allocated (by chance) to one particular type of operation.

If you decide you do not wish to be randomised, or your gynaecologist advises a particular type of operation would be best for you, you can still be part of the study. All women in the study, whether randomised or not, will complete the same questionnaires.

If I participate in the study how will I be followed up?

If you consent to take part in PROSPECT, you would not have to undergo any tests or procedures that are not part of NHS routine care for prolapse. Everyone in the study will be followed up in exactly the same way for two years initially but also hopefully in the longer-term as it is important to find out how you are quite some time after your prolapse operation.

You would return for a clinic appointment approximately 12 months after you have had your operation (randomised women only).

Also, we would send questionnaires to you at home for you to complete at 6, 12, 18 and 24 months after you joined the study. If you take part in the study and later change your mind, you can withdraw without giving a reason.

What will happen to the results of the study?

The results of the study will be used to advise on what type of prolapse surgery should be used to treat women in the future.

What happens next?

We will send you some more detailed information around the same time as you receive your hospital admission documents. You will then have a chance to speak to your gynaecologist and a member of the study team, who will be able to answer any queries you have.