<< DATE >>

Dr GPFName GPSName
GPAddress1
GPAddress2
GPAddress3
GPAddress4
GPPostCode

Patient Study Number:

Dear Dr

PROSPECT: PROlapse Surgery: Pragmatic Evaluation and randomised Controlled Trials

RE: Title FName SName DOB Address1 Address2 Address3 Address4 PostCode

A multicentre UK-wide research study, funded by the NHS National Institute for Health Research Health Technology Assessment Programme is investigating which prolapse operations are the safest and most clinical and cost-effective for women with anterior and/or posterior vaginal wall prolapse. CentreHosp is one of the participating sites. The trial is needed because there is uncertainty about which type of surgery is most effective for these women.

All women who consent will be followed-up and those who are eligible will be randomised to a particular type of surgery, depending on whether they are having their first operation or have had previous prolapse surgery. Both women who have had previous prolapse surgery and those having their first operation will be included. We are following up the women after their operations initially for two years, but hopefully long-term. More detailed information about the study is provided overleaf.

Your patient has agreed to join the study. She will either be followed up as part of the non-randomised cohort or may have been randomised to one of the surgery groups as appropriate for her. Her gynaecology consultant is ConsFName ConsSName.

We will carry out postal follow-up (from Aberdeen) by asking participants to complete questionnaires after surgery and at 6, 12 and 24 months later. The questionnaires ask about general health and use of the health service as well as specific information about prolapse symptoms. She will also be reviewed in outpatients by an appropriately qualified member of the research team or a gynaecologist 12 months following her surgery.

We should not normally need to obtain any information from you. However, we would be grateful if you could contact telephone number [redacted] your patient changes address, is too ill to continue taking part, has an adverse effect from prolapse surgery or dies.

If you would like to discuss any aspect of our trial, or require any further details, please do not hesitate to contact the PROSPECT Study Office on [redacted].

Yours sincerely

Dr Suzanne Breeman
PROSPECT Trial Manager

Prof Cathryn Glazener
PROSPECT Chief Investigator

~ PROSPECT GP INFORMATION SHEET

Title of project

Clinical and cost-effectiveness of surgical options for the management of anterior and/or posterior vaginal wall prolapse

Background

Around one in ten women will need prolapse surgery at some point in their lives. It is most common in women who have had children, although there has been surprisingly little research into its causes and treatment. A Cochrane review[1] and a NICE Interventional Procedures review[2] have identified that there is insufficient evidence to evaluate the effectiveness, cost-effectiveness and effect on quality of life of the different types of prolapse surgery, including whether mesh should be used.

There are numerous different operations for prolapse, depending on the type of prolapse, whether the woman is having her first or a secondary repair and the preference of the gynaecological surgeon. To date, there is a high failure rate after surgery: three in ten women who have an operation will have further surgery. This study will address anterior vaginal wall prolapse (cystocele, urethrocele) and posterior vaginal wall prolapse (rectocele, enterocele). Some women may need a concomitant procedure if there is uterine or vault prolapse (eg vaginal hysterectomy), or if she is incontinent (eg TVT).

Brief outline of the study

While the women are in hospital, they will have a routine physical examination before surgery and they will complete questionnaires both before and after their operation. Further symptom questionnaires will completed 6, 12 and 24 months later. The women will be examined and reviewed in outpatients at 12 months after surgery. Our main interest is in the cure or improvement of prolapse symptoms, as reported by the women themselves.

Ethical approval has been obtained for this study. The procedures used in the study will be standardised and agreed with a team of experienced gynaecologists from the British Society of Urogynaecology (RCOG).

The Researchers

The trial is being co-ordinated by the Centre for Healthcare Randomised Trials (CHaRT, a fully registered UK CRN clinical trials unit), at the Health Services Research Unit, University of Aberdeen. Gynaecologists in your local hospital have agreed to allow their patients who are having prolapse surgery to be invited to enter the study. All gynaecologists involved in this study will be experienced in each type of surgery to which their patients may be randomised.

If you have any questions about this study or the inclusion of your patient in it, please contact the PROSPECT Study Office in Aberdeen on [redacted].

References

1. C. Maher, K. Baessler, C. M. A. Glazener, E. Adams, and S. Hagen. Surgical management of pelvic organ prolapse in women (Cochrane Review). In: *The Cochrane Database of Systematic Reviews, Issue 3*,Anonymous Chichester, UK: John Wiley & Sons, Ltd., 2007,

2. X. Jia, C. M. A. Glazener, G. Mowatt, G. MacLennan, C. Fraser, and J. Burr. Systematic review of the efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: *http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11363*, 2008. 200 pages.